EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-11

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Storm Water
	Base Option Period Number 2	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: D. Analysis, Document, and Issue Paper Preparation

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/12/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2016		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Susan Julius (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8619 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-11

TITLE: Final Product -- Incorporating Climate Change into Stormwater Planning

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Specify Section & Paragraph SOW: Please select from the following:
D. Analysis, Document, and Issue Paper Preparation

PERIOD OF PERFORMANCE: *November 12, 2015 to 10/31/16*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the form of producing a final report and other outreach materials based on the results of three workshops held with municipalities in the Chesapeake Bay watershed last year to incorporate climate change into stormwater planning. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

This work assignment is a follow-on to work performed in the Base Period under Work Assignment # 0-11, and the first Option Period under Work Assignment # 1-11. The purpose of this work assignment is to provide continued services to the U.S. Environmental Protection Agency's (EPA) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of a final report based on the results of NOAA and EPA workshops held in the Chesapeake Bay and Great Lakes watersheds to incorporate climate change into stormwater planning. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA and over the course of 30 days, the Contractor shall schedule a series of bi-weekly conference calls (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Quality Assurance Project Plan (QAPP)

Because this rollover work assignment 2-11 is only deleting tasks from the previous work assignment 1-11, no new QAPP is needed. The previous QAPP, approved by the WAM and Quality Assurance Manager, is sufficient.

Task 3. Respond to External Review Comments and Produce Final Report

The Contractor shall produce a document responding to comments received from external letter reviews (3 reviewers), and from the public within 2 weeks of receiving the comments from the WAM. The WAM will review the responses and provide comments on the document to the Contractor. The Contractor shall make any necessary modifications to the comment-response (c-r) document based on feedback from the WAM, and shall revise the report based on the final approved c-r document. The Contractor shall provide the final c-r document to the WAM 1 week after receiving feedback from the WAM. The Contractor shall provide the final report to the WAM within 2 weeks of the WAM's approval of the final c-r document.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Calls	• 3 days after award of Work Assignment
Task 2. QAPP (previously approved)	• N/A
Task 3. Draft c-r document Final c-r document Final Report	• Draft c-r document due 2 weeks after receiving external review and public comments from the WAM • Final c-r document 1 week after receiving comments from the WAM • Final Report 2 weeks after approval of the final c-r document

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities

(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Task Order Manager (WAM)	**Alternate Task Order Manager (AWAM)**
Name: Susan Julius	Name: Britta Bierwagen
Office: ORD/NCEA/IO-GCAS 1200 Pennsylvania Ave., NW (MC 8601P) Washington, DC 20460	Office: ORD/NCEA/IO-GCAS 1200 Pennsylvania Ave., NW (MC 8601P) Washington, DC 20460
Phone: 703-347-8619	Phone: 703-347-8613
Fax: 703-347-8694	Fax: 703-347-8694
Email: julius.susan@epa.gov	Email: bierwagen.britta@epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

> FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
> VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
> INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
> RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
> UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
> CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-11

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Stormwater Planning

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	D. Analysis, Document, and Issue Paper Preparation

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/12/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$9,102.00	68
Total:	$9,102.00	68

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 12/02/2015	$9,102.00	68
Cumulative Approved:	$9,102.00	68

Work Assignment Manager Name: Susan Julius (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8619 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Gokes (Signature) 12/24/15 (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-12

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	(ExpoFIRST

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	B. Risk Assessment Methods

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name Jacqueline Moya (Signature) (Date)		Branch/Mail Code: Phone Number: 703-347-8539 FAX Number:
Project Officer Name Melissa Revely-Wilson (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name William Yates William Yates (Signature)	2/18/2016 (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-12

TITLE: Development of Exposure Factors Interactive Resource for Scenarios Tool **(ExpoFIRST)**

Specify Section & Paragraph SOW: B. Risk Assessment Methods

PERIOD OF PERFORMANCE: CO Approval – October 31, 2016

I. PURPOSE

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA) in developing an exposure scenarios tool.

II. BACKGROUND

In 2004, EPA/ORD/NCEA issued the document entitled *Example Exposure Scenarios*. The purpose of the document was to outline scenarios for various exposure pathways and to demonstrate how data from the 1997 version of the *Exposure Factors Handbook* could be applied for estimating exposures. A similar document focusing on childhood exposure was published in October 2014. Exposure scenarios are tools that help the assessor develop estimates of exposure, dose, and risk. An exposure scenario generally includes facts, data, assumptions, inferences, and sometimes professional judgment about how the exposure takes place. The example scenarios presented in the 2004 *Example Exposure Scenarios* document were selected to best demonstrate the use of the various key data sets in the 1997 *Exposure Factors Handbook*, and represented commonly encountered exposure pathways. An exhaustive review of every possible exposure scenario for every possible receptor population was not feasible and was not provided in the document.

Under WA 0-12 and 1-12, a beta version of the Exposure Factors Interactive Resource for Scenarios Tool (ExpoFIRST) was developed. The Exposure Scenarios Tool was designed to replace and update the 2004 *Example Exposure Scenarios* document using more recent information from the *Exposure Factors Handbook: 2011 Edition.* The tool allows users to develop a wider variety of scenarios than those provided in the 2004 document. Internal peer review was conducted and an external peer review tool was delivered under WA 1-12. The tool is undergoing an independent external usability review during the fall 2015.

III. STATEMENT OF WORK

A. Objective

The purpose of this work assignment is to incorporate comments received during the usability review and produce final version of the tool. This tool will be a key addition to the Exposure Factors module developed for EPA-Expo-Box.

B. Specific Requirements

Task 1: Workplan

The workplan shall describe how the work in this PWS shall be performed, with a schedule, budget, level of effort, and qualifications of personnel. The workplan shall include a schedule of deliverables and interim deliverables. The workplan shall reference the Quality Assurance Project Plan (QAPP) that was approved under WA 0-12 on 5/15/14. Any amendments to the QAPP shall be submitted with the workplan for EPA approval.

Task 2: Development of the Final Version of the Tool

EPA will be conducting an external usability peer review during the fall 2015 under a separate contract. The contractor shall review the comments and arrange a conference call with the EPA WAM to discuss the comments and clarify any questions they may have. The contractor shall incorporate comments obtained from the external review and submit a final version of the tool for EPA clearance and publication. The contractor shall address any comments that may arise from management clearance. The contractor shall produce a response to comments document summarizing how external comments were addressed.

V. SCHEDULE OF DELIVERABLES

Task 1: A work plan and any amendments to the QAPP shall be delivered 20 days after issuance. Within 1 week of approval of the work plan, the contractor shall hold a conference call with the EPA WAM.

Task 2: The contractor shall review the external comments within 1 week of receipt and arrange for a conference call with the EPA WAM to discuss the comments and clarify any questions. The contractor shall incorporate comments from the usability peer review within 4 weeks after the conference call with the EPA WAM. More time may be allowed in consultation with the EPA WAM if comments are more significant than originally expected. If any comments arise from the management clearance process, the contractor shall address them within one week.

VI. Management Controls

1. The contractor shall certify there is no conflict of interest. The contractor shall provide the following conflict of interest certification in the workplan:

> I certify that, to the best of my knowledge and belief, no actual, apparent, or potential organizational or individual conflicts of interest related to this work assignment exist. Personnel, who perform work under this work assignment, or relating to the work assignment, have been informed of their obligation to report personal and organizational interests. All actual, apparent or potential organizational or individual conflicts of interest related to this work assignment have been reported to the Project Officer or are attached, if applicable.

2. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

3. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

4. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in the contract.

VII. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

VIII. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

X. Work Assignment Manager (WAM)

Jacqueline Moya
US EPA (8623P)
National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460
Telephone #: (703) 347-8539
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Alternate WAM
Linda Phillips
National Center for Environmental Assessment
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1200 Pennsylvania Ave. NW
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EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-12

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Exposure Scenarios Tool

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	B - Risk Assessment Methods

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$15,222.00	184
Total:	$15,222.00	184

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 03/09/2016	$15,222.00	184
Cumulative Approved:	$15,222.00	184

Work Assignment Manager Name: Jacqueline Moya (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8539 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-13

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	EPA-Expo-Box
	Base Option Period Number 2	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	III. C.

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2016		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-13

TITLE: Technical Support for Revisions to EPA-Expo-Box (a toolbox for exposure assessors)

Specify Section & Paragraph SOW: III.C.

PERIOD of PERFORMANCE: 11/01/2015 through 10/31/2016.

I. PURPOSE.

The purpose of this work assignment is to obtain technical support services to the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) for revisions to EPA-Expo-Box (a toolbox for exposure assessors). This is a continuation of efforts conducted under work assignment 4-77 of contract number EP-C-09-009 and work assignments 0-13 and 1-13 of contract number EP-C-14-001.

II. BACKGROUND AND OBJECTIVES.

EPA-Expo-Box is an online toolbox for exposure assessors. It was developed by EPA's Office of Research and Development, National Center of Environmental Assessment (NCEA) to serve as a web-based compendium of exposure assessment tools. It is comprised of a series of Tool Sets, each containing modules that address exposure assessment topics. Toolbox modules contain descriptions of the topics and links to exposure assessment resources including databases, models, guidance documents, and other resources for exposure assessors. A search interface allows users to identify resources using keywords or topics. EPA-Expo-Box was originally released in Fall 2013 and a revision in the new Drupal format was recently released in 2015. Periodic maintenance of the Toolbox will be necessary to ensure that EPA-Expo-Box content and tool links remain current. Technical assistance will be required for updating EPA-Expo-Box as needed.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of five tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1. The contractor shall establish communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).

The contractor shall schedule an initial conference call **within 1 week** after the receipt of the work assignment. The call shall include the COR and relevant members of the ICF team.

Deliverable 1: The contractor shall arrange a conference call with the COR, **within 1 week after the receipt of the work assignment.**

Task 2. The contractor shall assist in correcting broken links in EPA-Expo-Box.

The migration of EPA-Expo-Box to the new Drupal format may result in broken links to tools identified in the Toolbox. The contractor shall conduct a minimum of 2 comprehensive reviews of the links in EPA-Expo-Box to identify and correct any broken links **at intervals to be designated by the COR in written technical direction**. **Within 2 weeks of receiving technical direction from the COR,** the contractor shall suggest replacement links for broken links and/or links to outdated tools. A record of these changes shall be maintained by the contractor using the tracking spreadsheet maintained under work assignments 0-13 and 1-13 of the contract.

Deliverable 2a: The contractor shall conduct a minimum of 2 comprehensive reviews of the links in the Master Tool List **at intervals to be designated by the COR in written technical direction.**

Deliverable 2b: The contractor shall provide replacement links for broken links and/or links to outdated tools **within 2 weeks of receiving technical direction from the COR.**

Task 3. The contractor shall assist in addressing comments on EPA-Expo-Box.

The contractor shall assist EPA in reviewing any comments received on the new version of EPA-Expo-Box, and formulating plans for addressing these comments. The contractor shall review comments provided by the COR. **Within 1 week after receiving comments from the COR**, the contractor shall arrange a conference call with the COR to discuss the comments and the next steps for making revisions to the Toolbox. The contractor shall prepare and submit to the COR draft responses **within 2 weeks of the COR assigning issues or topic areas** that will need to be addressed. For the purpose of preparing the work plan and cost estimate for this work assignment, the contractor shall assume that there are 3 key issues to be addressed, and that any other comments will require only minor revisions. The list of comments and their resolution that was maintained under work assignments 0-13 and 1-13 of this contract shall continue to be maintained in order to track revisions made to the Toolbox. This list will include key issues as well as other minor corrections.

Deliverable 3a: The contractor shall arrange a conference call with the COR **within 1 week after the receiving comments from the COR**.

Deliverable 3b: The contractor shall prepare responses to the issues **within 2 weeks of being assigned by the COR**.

Task 4. The contractor shall assist in updating EPA-Expo-Box content

Revisions to EPA-Expo-Box may occasionally be needed to reflect updated EPA exposure assessment policies or procedures. Based on technical direction from the COR, the contractor shall identify specific areas within EPA-Expo-Box that will require revision as a result of new policies or procedures and provide suggestions for implementing these changes to the Toolbox. The contractor shall provide the COR with a list of suggested

revisions **within 4 weeks of receiving technical direction from the COR regarding the necessary revisions.**

Deliverable 4a: The contractor shall provide the COR with a detailed list of suggested revisions **within 4 weeks after receiving technical direction from the COR.**

Task 5. The contractor shall provide information to update the Master Tool List

A Master Tool List for EPA-Expo-Box was developed previously under work assignment 4-77 of contract EP-C-09-009 and updated under work assignments 0-13 and 1-13 of EP-C-14-001. The purpose of this Master Tool List is to provide a comprehensive listing of all the tools included in the Toolbox, along with the descriptions, URLs, and key words associated with each tool. The Master Tool List also indentifies all of the Tool Sets, modules, and sub-modules within the toolbox where the tool is to be included. The Master Tool List forms the basis of EPA-Expo-Box's underlying data that is used for the following 2 purposes:

(1) to populate tables within each of the Tool Set modules that tools relevant to that topic area; and
(2) to allow the toolbox to be searched using key words via a user-friendly graphical user interface.

The contractor shall provide the necessary information to revise and update the Master Tool List, as needed, to correct broken links (Task 2), to incorporate any new tools that have been identified from comments on the Toolbox (see Task 3), and to add tools based on the revision of existing content (Tasks 4). The contractor shall also ensure that any new or updated tools have been appropriately assigned to the various Tool Sets, modules, and sub-modules (many of the tools will be applicable in more than one module or sub-module), and that accurate tool descriptions and key words are provided. The contractor shall submit all of the draft information necessary to revise and update the Master Tool List to the COR **within 2 weeks after completing Tasks 2, 3, and 4** for comment by the COR. **Within 1 week after receiving comments from the COR**, the contractor shall submit the final information necessary to update the Master Tool List.

Deliverable 5a: The contractor shall submit to the COR draft information necessary to revise and update the Master Tool List **within 2 weeks after completing Tasks 2, 3, and 4.**

Deliverable 5b: The contractor shall submit the final information necessary to update the Master Tool List to the COR **within 1 week after the receipt of the COR's comments on Deliverable 5a**.

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

.IV. TIME TABLE.

Task	Deliverable	Time frame
1a	Establish communication via conference call	Within 1 week after receipt of work assignment
2a	Review Toolbox links	At intervals to be designated by COR
2b	Provide replacement links	Within 2 weeks of receiving technical direction from the

		COR
3a	Review comments and conduct conference call	Within 1 week of receiving comments from the COR
3b	Prepare responses to issues or topic areas	Within 2 weeks of being assigned by COR
4a	Submit revised content	Within 4 weeks of being assigned by COR
5a	Submit draft information for Master Tool List	Within 2 weeks after completing Tasks 2, 3, and 4
5b	Submit final information for Master Tool List	Within 1 week of COR comments

1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).

3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.

4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

Work Assignment Manager	**Alternate WAM**
Linda Phillips US EPA (8623P) National Center for Environmental Assessment	Jacqueline Moya US EPA (8623P) National Center for Environmental Assessment

Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-0366 FAX #: (703) 347-8690 Email: phillips.linda@epa.gov	Office of Research and Development U.S. Environmental Protection Agency 1200 Pennsylvania Ave. NW Washington, DC 20460 Telephone #: (703) 347-8539 FAX #: (703) 347-8694 Email: moya.jacqueline@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-13

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	EPA-Expo-Box
	Base Option Period Number 2	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	III.C.

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$17,811.00	218
Total:	$17,811.00	218

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated: 11/19/2015	$17,811.00	218
Cumulative Approved:	$17,811.00	218

Work Assignment Manager Name: Linda Phillips (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0366 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-14

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Microbial Data Usability
	Base Option Period Number 2	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B2

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period:	Cost/Fee:	LOE:
	11/01/2013 To 10/31/2016		
This Action:			
Total:			

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name: Cynthia Yund (Signature) (Date)	Branch/Mail Code: Phone Number: 513-569-7779 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-14

TITLE: Development of Tool for Microbial Data Usability for Environmental Decision Making

Specify Section & Paragraph SOW: B2. Support research, development, and application of new risk assessment methods suitable for either conducting or evaluating cumulative risk, microbial risk, mixtures risk, dose-response assessment (including extrapolation to low dose), exposure assessment, and relevant uncertainty analysis.

Period of Performance: November 1, 2015 – October 31, 2016

I. OBJECTIVES

The main objective of this Work Assignment (WA) is to support a new U.S. Environmental Protection Agency (EPA) tool for determining data usability requirements needed for environmental data collection and analysis of microbial samples for decision making. The tool will provide microbial data collectors, analyzers, and decision makers a standardized basis for the required quality and quantity of environmental data sufficient to support risk-based remedial decisions.

II. BACKGROUND

The EPA-NHSRC was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, the EPA-NHSRC's Threat and Consequence Assessment Division (TCAD) is responsible for assessing potential exposures associated with the intentional release of hazardous and toxic materials including chemical, biological, and nuclear threat agents. TCAD is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of the TCAD is the applications of microbial environmental assessment methodologies utilized to support cleanup decision making regarding cleanup goals, treatment technology efficacies, and detection limits during biological contamination incidents.

The EPA developed the *Guidance for Data Usability in Risk Assessment Parts A and B* (U.S. EPA, 1992a and 1992b) to offer guidance for chemical (Part A) and radionuclides (Part B) data collection and analysis. However, there is currently no similar guidance for microbial samples available for the EPA responders and managers who lead the site data collection or for the personnel who must interpret the data analysis for the site decision makers.

III. TASKS

Task 1: <u>Establish Communication</u>

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the Work Assignment Contracting Officer Representative (WA-COR) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The contractor shall generate a workplan that follows on work completed in the first performance period, describing how tasks 2-6 shall be

performed. The workplan shall include the overall project purpose, scope, and approach. Each task shall be described in detail including the specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations.

Within the workplan, the contractor shall deliver to the EPA WA-COR a Project Management file outlining the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships.

The contractor shall ensure adherence in the workplan to the existing approved Quality Assurance Project Plan developed under the previous year funding (WA2-14).

Deliverables: Conference Call and Project Management file

Performance Standard: The contractor shall provide the draft workplan containing projected tasks' specifics requested within 30 days of award.

Task 2: Data Usability Guidance for Microbial Samples Working Group Meetings Preparation, Organization, Facilitation, and Summary Reports

The contractor shall organize, manage, and summarize 4-6 technical working group meetings by webinar for the new guidance.

1. The contractor shall meet with the WA-COR to discuss substantive, procedural and process design issues and define the workgroup members and other potentially involved interests and parties and further refine qualifications for the service provider.

2. The contractor shall select professionals for this project in consultation with the WA-COR. The appropriate professionals for this project will have a background in microbial environmental sampling, microbial data analysis, and/or risk assessment,

3. The contractor shall work with WA-COR to identify the goals and purpose of the meetings, the issues involved, group relationships and interactions, timing and schedule for reports or activities.

4. The contractor shall work with the WA-COR to propose a design and schedule for the meetings. Upon approval of the WA-COR, the contractor shall implement the design.

5. The contractor shall facilitate the meeting per the project design and assist participants in articulating their interests, identifying areas of agreement, and recommendations for additional studies. As facilitator, s/he shall keep the parties talking, listening, and moving--as much as possible-- towards the goal of the meeting and assist the group in overcoming impasse. **THE FACILITATOR WILL NOT TAKE POSITIONS ON THE MERITS NOR RECOMMEND TO THE GROUP WHAT THE SUBSTANTIVE RESOLUTION OF AN ISSUE SHOULD BE.**

6. The contractor shall provide a draft agenda to the WA-COR for the meeting after consulting the WA-COR on needs and goals of the meeting.

7. The contractor shall communicate as necessary in person, by phone, or in writing, with the WA-COR to ensure that issues and concerns have been communicated accurately and that everything is adequately prepared for the meeting. Material shall be provided for approval at least 5 business days prior to the meetings.

8. The contractor shall provide draft meeting summaries to the WA-COR and meeting participants per the approved project design.

9. The contractor shall write the annual meeting summary report per the project design. This may include collecting and incorporating comments, suggestions and changes from the parties, circulating drafts and managing discussion of comments, researching and providing information, data and recommendations to the parties, assisting in design of the document and guidelines for comments.

10. The contractor shall provide subject matter experts in the field of microbial risk assessment, microbial environmental sampling and lab analytics, and microbial data analysis. The subject matter experts shall perform the following tasks under the specific supervision of the WA-COR and the general direction of the workgroup participants:
    a. Review preliminary product and background materials.
    b. Provide in depth recommendations for revisions of the products as described below.

Deliverable: 3-5 Technical Expert Meetings and Meeting Reports

Performance Standard: The contractor shall facilitate the first meeting within 1 month after approval of work plan.

Task 3: Framework for Online Data Usability Tool for Microbial Samples in Decision Making

The contractor shall develop, revise, and update the data usability product for microbial samples based off of the expert working group input received during and after the technical meetings. The contractor shall provide scientific and technical support under the direction of the WA-COR for the development of this product. The proposed scientific and technical authors shall be primarily EPA personnel who provide specific knowledge, expertise and experience needed for the new product. This new documentation must be nationally recognized as scientifically sound and authoritative. The contractor shall propose the new product outline and some content at the working group meetings. The contractor shall provide subsequent drafts based off of input from the technical experts obtained from meetings. The contractor shall present any revisions and reviews of the draft product once reviewed by the workgroup.

The document framework will be built by the workgroup group. *Guidance for Data Usability in Risk Assessment Parts A and B* (U.S. EPA, 1992a and 1992b) shall be used as a primary reference point. It is anticipated that content is to be revised and finalized during this option period. The content shall be developed with the intent a final product shall be in a modular web-based format. The modules may include topics such as:

Module A: Data Quality Objective Process and Quality Assurance Plans
- A1 Problem Definition and Background;
- A2 Data Quality Objectives and Criteria;

A3 Quality Assurance Plan.

Module B: Data Management (Generation, Acquisition, Reporting)

B1 Sampling Methods;
B2 Analytic Considerations;
B3 Data Review, Verification and Validation
B4 Statistical Considerations

Module C: Quality Assessment and Oversight; will be incorporated into both Module A and Module B rather than be treated as a separate module

C1 Quality Assessments; and
C2 Reports to Management.

Online tools are most effective when the frame work for the tool is developed concurrently with the tool content. It is expected that the contractor will use the Volte process for designing the online tool as described in Work Assignment no 1-14, Amendment 2. It is expected a functional tool will be ready for expert testing by the end of this contract period.

Deliverable: Draft Framework for Data Usability for Microbial Samples in Decision Making Web-based Tool

Performance Standard: The contractor shall revise the content of the proposed microbial data usability tool within 1 month after the third technical work group meeting. The contractor shall develop the draft framework for the web based tool for review during the face to face meeting. A revised draft of the web-based tool framework shall be completed within 6 months of the face to face meeting.

Task 4: Example Use of Framework for Data Usability Tool for Microbial Samples in Decision Making

The contractor shall use *B.anthracis* as an example to populate the data usability product for microbial samples based off of the expert working group input and current state of scientific knowledge. The contractor shall provide scientific and technical support under the direction of the WA-COR for the development of this product. This new documentation must be nationally recognized as scientifically sound and authoritative. The contractor shall propose the content according to the working group suggestions. The contractor shall provide subsequent drafts based off of input from the technical experts. The contractor shall present any revisions and reviews of the draft product to the WA-COR.

Deliverable: Example use for Data Usability for Microbial Samples in Decision Making Web-based Tool

Performance Standard: The contractor shall present an example of the Data Usability Tool for Microbial samples and a sample Quality Assurance Plan using B. anthracis as an example within 8 months after the face to face work group meeting. A revised draft of the example shall be completed within 2 months of the draft document.

Task 5: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WA-COR and the contractor to keep EPA-NHSRC updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to EPA-NHSRC on request within two weeks of the request.

The contractor shall also submit combined technical and financial monthly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of EPA-NHSRC. All documents or presentations associated with this project shall be cleared through EPA-NHSRC prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by EPA-NHSRC WA-COR prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to EPA-NHSRC. EPA-NHSRC shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to EPA-NHSRC WA-COR with responses and dispositions of comments.

All references cited in submitted reports and deliverables to EPA-NHSRC shall be provided to EPA-NHSRC either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to EPA-NHSRC. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by EPA-NHSRC, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in a compatible electronic format, such as EndNote as well as a paper hard copy of the references. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit monthly reports.

IV. PERFORMANCE PERIOD

The performance period is 12 months from the date of award.

V. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method
1	Conference Call	Contractor shall provide the completed workplan within 30 days of award	WA-COR shall document whether receipt of workplan is timely and acceptable and provide technical revisions as required
2	Working Group Meetings Preparation, Organization, Facilitation, and Summary Reports	Contractor shall conduct 4-7 (includes annual meeting) technical expert working group meetings and develop the associated meeting reports. Contractor shall conduct the first meeting within 1 month of the workplan and any revised QAPP approval.	WA-COR shall participate in these meeting identify any issues to be addressed in the research or future reports
3	Data Usability Tool for Microbial Samples Draft Framework	The contractor shall develop the draft tool framework within 2 months after the face to face meeting	WA-COR shall document the receipt of this draft framework, and ensure that it is timely and technically acceptable. Technical comments shall be provided through the WA-COR after review of the work group.
4	Example Data Usability Tool for Microbial Samples	The contractor shall develop in conjunction with the tool framework a specific example of its use with *B. anthracis*. A draft shall be completed within 8 months of approval of the workplan.	WA-COR shall document the receipt of this example and ensure that it is timely and technically acceptable and provide technical comments as appropriate
5	Communications and Progress Reports	Bi weekly conference calls between ICF and EPA WA-COR Monthly Reports	Every 2 weeks Monthly

VI. INTELLECTUAL PROPERTY

All methods, models and tools developed by the contractor and/or provided to the contractor under this WA is the intellectual property of the EPA-NHSRC. All data collected and analyzed under this WA is the intellectual property of the EPA-NHSRC.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

1. Formulation of Agency policy
2. Selection of Agency priorities
3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent of real personal or organizational conflict of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA-COR)

Cynthia Yund, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7779

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the

Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP: QAPP** requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the **NHSRC's QMP QAPP** requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001
http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA ID	Quality Assurance Identification
QAPP	Quality Assurance Project Plan
QS	Quality System
TLP	Technical Lead Person
IAG	Interagency Agreement
QA	Quality Assurance
QAM	Quality Assurance Manager
QMP	Quality Management Plan
SOW	Statement of Work
CRADA	Cooperative Research & Development Agreement

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-14

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Tool for Microbial Data Usabil

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	B. 2

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (Max 2): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period 11/01/2013 To 10/31/2016		
This Action		
Total		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated		
Cumulative Approved		

Work Assignment Manager Name: Cynthia Yund (Signature) (Date)		Branch/Mail Code: Phone Number: 513-569-7779 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)		Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number
Contracting Official Name: Adam Meier (Signature)	10-28-15 (Date)	Branch/Mail Code: Phone Number: 513-487-2052 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-14

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base X Option Period Number	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW:

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$0.00	0
Total:	$0.00	0

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 01/27/2016	$0.00	0
Cumulative Approved:	$0.00	0

Work Assignment Manager Name: Cynthia Yund (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-569-7779
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2852
	FAX Number:	513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-14

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Microbial Sample Data
	Base Option Period Number 2	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: B. 2

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:
This amendment removes Cynthia Yung as the WAM and replaces her with Erin Silvestri, the new Alt. COR is Kathy Hall.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
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Authorized Work Assignment Ceiling

	Cost/Fee:	LOE:
Contract Period: 11/01/2013 To 10/31/2016		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Erin Silvestri (Signature) (Date)		Branch/Mail Code: Phone Number: 513-569-7619 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)		Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2017 Base Option Period Number 2	EVIDENCE TABLES

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A Assessment Issues and Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2017 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2289 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-15

TITLE: PREPARATION OF EVIDENCE TABLES FOR THE IRIS DRAFT TOXICOLOGICAL REVIEW OF POLYCHLORINATED BIPHENYLS (PCBs): EFFECTS OTHER THAN CANCER (CAS NO. 1336-36-3)

Specify Section & Paragraph SOW: Section A (Assessment Issues and Documents), Subsection 1 (Human Health Assessment Documents)

PERIOD OF PERFORMANCE: 11/1/15 to 10/31/16

I. PURPOSE

This work assignment is a follow-on to work performed under Work Assignment 1-15. The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of updating the existing draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer (hereinafter the draft Toxicological Review). Specifically, support will include developing evidence tables for the draft Toxicological Review on the potential non-cancer health hazards of PCBs (by all routes of exposure) and conducting literature updates relevant to this assessment. The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential non-cancer health effects from PCBs by all exposure routes. All applicable Agency guidance and formats should be used in the development of this draft document.

II. BACKGROUND

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral RfDs and inhalation RfCs for chronic noncancer health effects, as well as cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

The IRIS process for assessment development follows the process implemented in May 2009, including enhancements announced in July 2013 (http://www.epa.gov/iris/process.htm): a comprehensive literature search, a public

problem formulation meeting, and development of a draft Toxicological Review (Step 1 of the IRIS Assessment Development Process); internal Agency review (i.e., within EPA) (Step 2); science consultation with other federal agencies and White House offices (i.e., interagency review) (Step 3); public review and comment and independent expert peer review (i.e., outside EPA) (Step 4); revision of the IRIS assessment and preparation of the IRIS Summary (Step 5); final internal Agency review (i.e., within EPA) and science discussion with other federal agencies and White House offices (i.e., interagency review) (Steps 6A and 6B); and posting the final Toxicological Review and IRIS Summary on the IRIS database (Step 7).

This Performance Work Statement (PWS) addresses Step 1 of the IRIS process for assessment development: development of the draft Toxicological Review. An initial draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer has been written. However, it is now necessary to update the existing draft and to develop materials (literature search strategies, evidence tables, and exposure-response figures) for release to the public for discussion at a problem formulation meeting.

In developing the Toxicological Review, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2000)
- *Use of the Benchmark Dose Approach in Health Risk Assessment* (U.S. EPA, 1995)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)
- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006).

III. STATEMENT OF WORK

This work assignment is a direct follow-on to WA 1-15 received under the same contract. This statement of work has been amended to reflect the completion of some tasks under WA 1-15

Task 1: Establish Communication

This task was completed under WA 1-15. No further work is expected under this task.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

This task was completed under WA 1-15, and the work plan and QAPP for WA 2-15 have not changed substantively. No further work is expected under this task.

Task 3: Literature Review

The task initiation meeting for Task 3 was completed under WA 1-15.

The Contractor shall screen PCB literature within EPA's HERO database to identify studies of relevance to the IRIS assessment. Determination of relevancy shall initially be based on study title and abstract or other information according to criteria developed in collaboration with the EPA WAM (see below). For each relevant study, the Contractor shall determine appropriate categories, selecting from a list to be developed by the Contractor in collaboration with the EPA WAM (see below). The Contractor shall assign tags in HERO based on the identified categories. After tagging references in EPA's HERO database, the Contractor shall generate the literature flow diagram.

Relevant literature includes studies related to health effects in animals and humans resulting from acute, subchronic, and chronic exposure durations, and from all routes of exposure. The Contractor shall identify data specifically useful for addressing risks to the general population, susceptible populations, and from exposure during particular periods of development (i.e., lifestages). Characteristics of susceptible populations might include age, sex, smoking status, pre-existing disease, genetic polymorphisms, socioeconomic status, race and ethnicity, body mass index, alcohol consumption, nutritional factors, and co-exposure to other chemical stressors. The Contractor shall include other relevant studies such as in vitro studies related to mechanism of action; studies of absorption, distribution, metabolism, and elimination; and models useful for dose-response assessment such as dosimetry, pharmacokinetic (PK), and physiologically-based pharmacokinetic (PBPK) models.

Preliminary criteria for study inclusion/exclusion and study categories will be discussed at the task initiation meeting. Within a week of this meeting, the Contractor and EPA WAM shall, in parallel, screen a test set of approximately 200 references. The Contractor shall hold a second meeting with the EPA WAM approximately one week after the task initiation meeting to discuss the results of the test set screening. These results will be used to determine study inclusion/exclusion criteria and study categories to be used by the Contractor for screening the remaining PCB literature. As work progresses on this task, the Contractor shall periodically consult with the EPA WAM to discuss the appropriate characterization of any studies for which inclusion/exclusion or appropriate study category is unclear.

The literature test set screening was completed under WA 1-15.

Additional literature review will include elements of systematic review, including evaluation of study quality where needed. The results of any study quality analysis shall be included in the literature review product. Literature review shall be updated

periodically as new literature is added to EPA's HERO database.

Task 4: Preparation of Evidence Tables

The Contractor shall provide support to EPA in preparing evidence tables that summarize organ-specific toxicity in human studies and animal bioassays. The evidence tables will be generated using the Dose Response Analytical Generator and Organizational Network (DRAGON) Tool.

Task 4a: Human Studies

Evidence tables shall be prepared for non-cancer human data identified in Task 3. The studies shall be sorted by health effect category, with separate tables for each category; studies may be in more than one table. Data from each study will be entered into the DRAGON Tool, which will then be used to generate the evidence tables. The Contractor shall initially provide the WAM with sample evidence tables for each health effect category, each populated with data from no more than 10 human studies, providing design and population details, outcome assessment details, exposure measures, and results for each study. The studies included in the sample evidence tables shall be selected to represent a variety of study designs to illustrate the proposed format for display of data from different types of studies (e.g., studies of populations exposed from different sources (occupational, fish consumption, general population exposure), and studies using different epidemiological designs (cross-sectional, longitudinal, case-control)). The WAM will review the sample tables and provide feedback that will be used to guide the development of complete human study evidence tables (i.e., containing data from all of the relevant human studies identified in Task 3), which will also be provided to the WAM for review. As the complete tables are developed, the Contractor shall periodically consult with the EPA WAM to discuss the table entry format for study types that were not included in the sample tables or whenever the Contractor is unsure about the best format to display data for a given study. EPA will provide the Contractor with comments on the complete human study evidence tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Sample evidence tables were completed under WA 1-15.

Task 4b: Animal Studies

Concurrent with the development of evidence tables for non-cancer human exposure data in Task 4a, data from subchronic, chronic, reproductive and developmental animal toxicity studies identified in Task 3 shall be summarized in evidence tables sorted by health effect category. Separate sets of tables summarizing information from oral and inhalation exposure studies shall be prepared. Data from each study will be entered into the DRAGON Tool, which will then be used to generate the evidence tables. The Contractor shall initially provide the WAM with sample evidence tables for each health effect category, each populated with data from no more than 10 animal studies, providing study design details, outcome assessment details, exposure measures, and results for each study. The studies included in the sample evidence tables shall be selected to represent a

variety of study designs to illustrate the proposed format for display of data from different types of studies (e.g., different routes of exposure (oral, inhalation, dermal), different exposure paradigms (subchronic, chronic, multigenerational)). The WAM will review the sample tables and provide feedback that will be used to guide the development of complete animal study evidence tables (i.e., containing data from all of the relevant animal studies identified in Task 3), which will also be provided to the WAM for review. As the complete tables are developed, the Contractor shall periodically consult with the EPA WAM to discuss the table entry format for study types that were not included in the sample tables or whenever the Contractor is unsure about the best format to display data for a given study. EPA will provide the Contractor with comments on the complete animal study evidence tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Sample evidence tables were completed under WA 1-15.

Task 5: Preparation of Absorption, Distribution, Metabolism, and Excretion (ADME) Inventory Tables and Synthesis Text

The task initiation meeting for Task 5 was completed under WA 1-15.

Task 5a: Develop Inventory Tables

Using data from studies identified in Task 3, the Contractor shall prepare tables summarizing the available evidence pertaining to absorption, distribution, metabolism, and excretion (ADME) of PCBs. Tabular presentation of pharmacokinetic (PK) and ADME data can provide the reader with a means of rapidly understanding the depth and breadth of available data. Emphasis should be placed on communicating the study design, including in vitro or in vivo, and the range of doses and time points studied. Additional information should convey the species, strain and sex of animals studied, the PCB mixture or specific congeners tested, and the time points evaluated. When available, the identification of parent compound and metabolites should be included. Finally, the conclusions supported by the available evidence should be communicated along with any notable limitations of the study.

The inventory tables for PCBs will be generated using the DRAGON Tool. The EPA WAM will provide materials (i.e., instructions and examples) to the Contractor to guide the development of the table structure for this task. The Contractor shall initially provide the WAM with sample inventory tables for each pharmacokinetic process (i.e., absorption, distribution, metabolism, and excretion), each populated with data from 3 to 5 studies. The WAM will review the sample tables and provide feedback that will be used to guide the development of complete ADME inventory tables, which will also be provided to the WAM for review. EPA will provide the Contractor with comments on the complete ADME inventory tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Task 5b: Develop Synthesis Text

The Contractor shall also develop synthesis text describing the available ADME data associated with exposure to PCBs. The synthesis section shall conform to the style and the form of the revised IRIS format. The draft synthesis shall be delivered to the EPA WAM for review. EPA will provide the Contractor with comments on the draft synthesis text. The Contractor shall address EPA comments in a revised draft and deliver the revised document to the EPA WAM. This text shall be updated as new data become available.

Task 6: Assemble Hazard Identification and/or Dose-Response Conclusions from Other Governmental or International Risk Assessment Bodies

The Contractor shall develop a table of hazard identification and/or dose-response conclusions for PCBs developed by other governmental (e.g., ATSDR, FDA) or international (e.g., IARC, WHO) risk assessment bodies. The Contractor shall research which governmental and/or international risk assessment bodies have assessments for PCBs, extract the information of interest, and summarize that information in a table. EPA will provide the table structure for this task. The Contractor shall submit the draft table to the EPA WAM for review. EPA will provide the Contractor with comments on the draft table. The Contractor shall address EPA comments in a revised version of the table and deliver the revised document to the EPA WAM.

Task 7: Preparation of Synthesis Text to Describe the Evidence for Susceptible Populations and Lifestages

Prior to beginning work on Task 7, the Contractor shall hold a task initiation meeting with the EPA WAM to discuss the approach, products, and expectations.

Using data from studies identified in Task 3, the Contractor shall develop synthesis text summarizing the available evidence useful for addressing risks to susceptible populations and specific lifestages. Characteristics of susceptible populations might include age, sex, smoking status, pre-existing disease, genetic polymorphisms, socioeconomic status, race and ethnicity, body mass index, alcohol consumption, nutritional factors, and co-exposure to other chemical stressors. The synthesis section shall conform to the style and the form of the revised IRIS format. The draft synthesis shall be delivered to the EPA WAM for review. EPA will provide the Contractor with comments on the draft synthesis text. The Contractor shall address EPA comments in a revised draft and deliver the revised document to the EPA WAM. This text shall be updated as new data become available.

Task 8: Preparation of Inventory Tables and Synthesis Text to Describe the Evidence for Potential Modes of Action

The task initiation meeting for Task 8 was completed under WA 1-15.

Task 8a: Develop Inventory Tables

Using data from studies identified in Task 3, the Contractor shall prepare tables summarizing the available evidence considered for potential modes of action for PCBs.

Tabular presentation of mode of action (MOA) data can provide the reader with a means of rapidly understanding the depth and breadth of available data. Emphasis should be placed on communicating the study design, including in vitro or in vivo, and the range of doses and time points studied. Additional information should convey the model system used (e.g., species, strain and sex of animals, cell line or type for in vitro studies), the assays performed, the PCB mixture or specific congeners tested, and the time points evaluated. When available, the identification of parent compound and metabolites should be included. Finally, the conclusions supported by the available evidence should be communicated along with any notable limitations of the study.

The inventory tables for PCBs will be generated using the DRAGON Tool. The Contractor shall develop the table structure for this task in collaboration with the EPA WAM, using the structure for the ADME inventory tables as a starting point and organizing studies according to MOA categories discussed at the task initiation meeting. The Contractor shall initially provide the WAM with a sample inventory table, including one or two studies for each MOA category (e.g., genotoxicity, receptor-mediated, oxidative stress). The WAM will review the sample tables and provide feedback that will be used to guide the development of complete MOA inventory tables, which will also be provided to the WAM for review. EPA will provide the Contractor with comments on the complete MOA inventory tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Task 8b: Develop Synthesis Text

The Contractor shall also develop synthesis text describing the available MOA data associated with exposure to PCBs. The text will include discussions of overarching modes of action (e.g., aryl hydrocarbon receptor activation) as well as hypotheses connecting these modes of action with the specific health effects observed with PCB exposure. The synthesis section shall conform to the style and the form of the revised IRIS format. The draft synthesis shall be delivered to the EPA WAM for review. EPA will provide the Contractor with comments on the draft synthesis text. The Contractor shall address EPA comments in a revised draft and deliver the revised document to the EPA WAM. This text shall be updated as new data become available.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word or other format, as indicated. The literature search and electronic copies of the literature shall be provided via an Endnote database and uploaded to HERO.

V. DELIVERABLES AND SCHEDULE

TASK	DELIVERABLES
Task 1. Establish Communication	***Completed under WA 1-15***

TASK	DELIVERABLES
Task 2. Work Plan, Staffing Plan, and QAPP	***Completed under WA 1-15***
Task 3. Literature Review Products	**Task 3 initiation meeting:** ***Completed under WA 1-15*** **Literature test set screening:** ***Completed under WA 1-15*** **All studies tagged to categories in HERO and literature flow diagram completed:** 90 days following Task 3 initiation meeting for literature review Each update will be due 30 days after notification of a HERO update by EPA
Task 4a & 4b. Preparation of Evidence Tables	**Sample evidence tables for human and animal studies:** ***Completed under WA 1-15*** **Complete evidence tables for human studies (Task 4a):** provided to the WAM as they are completed, but no later than 120 days after EPA approval of the literature review product (Task 3) and EPA providing feedback on the sample evidence tables for human studies **Revised evidence tables for human studies (Task 4a):** 30 days after receiving EPA comments on complete evidence tables for human studies **Complete evidence tables for animal studies (Task 4b):** provided to the WAM as they are completed, but no later than 120 days after EPA approval of the literature review product (Task 3) and EPA providing feedback on the sample evidence tables for animal studies **Revised evidence tables for animal studies (Task 4b):** 30 days after receiving EPA comments on complete evidence tables for animal studies

TASK	DELIVERABLES
	Updates for Tasks 4a & 4b: 30 days after notification of a HERO update by EPA
Task 5a & 5b. Preparation of Absorption, Distribution, Metabolism, and Excretion (ADME) Inventory Tables and Synthesis Text	**Task 5 initiation meeting:** ***Completed under WA 1-15*** **Sample inventory tables for ADME studies:** 30 days after EPA approval of the literature review product (Task 3) **Complete ADME inventory tables (Task 5a):** 90 days after receiving EPA comments on sample inventory tables **Revised ADME inventory tables (Task 5a):** 30 days after receiving EPA comments on complete ADME inventory tables **Draft synthesis text (Task 5b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 5b):** 30 days after receiving EPA comments on draft synthesis text **Updates for Tasks 5a & 5b:** 30 days after notification of a HERO update by EPA
Task 6. Assemble Hazard Identification and/or Dose-Response Conclusions from Other Governmental or International Risk Assessment Bodies	**Draft table:** 120 days after EPA approval of the literature review product (Task 3) **Revised table:** 30 days after receiving EPA comments on draft table
Task 7. Preparation of Synthesis Text to Describe the Evidence for Susceptible Populations and Lifestages	**Task 7 initiation meeting:** 15 days after EPA approval of the literature review product (Task 3) **Draft synthesis text:** 90 days following Task 7 initiation meeting **Revised synthesis text:** 30 days after receiving EPA comments on draft synthesis text

TASK	DELIVERABLES
	Each update will be due 30 days after notification of a HERO update by EPA
Task 8a & 8b. Preparation of Inventory Tables and Synthesis Text to Describe the Evidence for Potential Modes of Action	**Task 8 initiation meeting:** ***Completed under WA 1-15*** **Sample inventory tables for MOA studies:** 30 days after submitting complete evidence tables for human and animal studies **Complete MOA inventory tables (Task 8a):** 90 days after receiving EPA comments on sample inventory tables **Revised MOA inventory tables (Task 8a):** 30 days after receiving EPA comments on complete MOA inventory tables **Draft synthesis text (Task 8b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 8b):** 30 days after receiving EPA comments on draft synthesis text **Updates for Tasks 8a & 8b:** 30 days after notification of a HERO update by EPA

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The Contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy

(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

X. Work Assignment Manager (WAM)

Geniece M. Lehmann, Ph.D.
Telephone: 919-541-2289
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Research Triangle Park, NC 27711

Other Delivery Address:
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Alternate Work Assignment Manager:

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Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	PREPARATION OF EVIDENCE TABLES

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 02/01/2016 To 10/31/2016

Comments:
Added tasks 9-10

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2016		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-2289 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates William Yates (Signature)	2/09/2016 (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
Amendment 1 to WA 2-15

TITLE: PREPARATION OF EVIDENCE TABLES FOR THE IRIS DRAFT TOXICOLOGICAL REVIEW OF POLYCHLORINATED BIPHENYLS (PCBs): EFFECTS OTHER THAN CANCER (CAS NO. 1336-36-3)

Specify Section & Paragraph SOW: Section A (Assessment Issues and Documents), Subsection 1 (Human Health Assessment Documents)

PERIOD OF PERFORMANCE: CO Approval to 10/31/16

I. PURPOSE

The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of updating the existing draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer (hereinafter the draft Toxicological Review). The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential non-cancer health effects from PCBs by all exposure routes. All applicable Agency guidance and formats should be used in the development of this draft document. ***This amendment provides for continuation and extension of work initiated under Contract EP-C-14-001 WA 2-15.***

II. BACKGROUND

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral RfDs and inhalation RfCs for chronic noncancer health effects, as well as cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

The IRIS process for assessment development follows the process implemented in May 2009, including enhancements announced in July 2013 (http://www.epa.gov/iris/process.htm): a comprehensive literature search, a public problem formulation meeting, and development of a draft Toxicological Review (Step 1 of the IRIS Assessment Development Process); internal Agency review (i.e., within EPA)

(Step 2); science consultation with other federal agencies and White House offices (i.e., interagency review) (Step 3); public review and comment and independent expert peer review (i.e., outside EPA) (Step 4); revision of the IRIS assessment and preparation of the IRIS Summary (Step 5); final internal Agency review (i.e., within EPA) and science discussion with other federal agencies and White House offices (i.e., interagency review) (Steps 6A and 6B); and posting the final Toxicological Review and IRIS Summary on the IRIS database (Step 7).

This Performance Work Statement (PWS) addresses Step 1 of the IRIS process for assessment development: development of the draft Toxicological Review. An initial draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer has been written. However, it is now necessary to update the existing draft and to develop materials (literature search strategies, evidence tables, and exposure-response figures) for release to the public for discussion at a problem formulation meeting.

In developing the Toxicological Review, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2000)
- *Use of the Benchmark Dose Approach in Health Risk Assessment* (U.S. EPA, 1995)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)
- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006).

III. STATEMENT OF WORK

This amendment alters the following tasks:

Task 1: Establish Communication

This task was completed under WA 1-15. No further work is expected under this task.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in amended Tasks 9-10 will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, and that shows assigned personnel by task and the qualifications of the proposed personnel.

The Contractor shall update the existing Quality Assurance Project Plan (QAPP) that was approved for EPA Contract EP-C-14-001 Work Assignment 1-15 (ICF Reference Number 130619.1.015.00, dated 07/08/2015). The Contractor shall submit the updated version to the EPA WAM and Quality Assurance Manager simultaneously with the Work Plan for approval. The Contractor shall not perform any work on amended Tasks 9-10 until the Work Plan and updated QAPP are reviewed and approved.

The work plan for Tasks 3-8 has not changed substantively. The Contractor is not required to submit a new work plan for these unaltered tasks.

Task 9: Development of Tool for the Assessment of PCB Mixture Similarity

Prior to beginning work on Task 9, the Contractor shall hold a task initiation meeting with the EPA WAM and other interested parties within EPA to discuss the approach, products, and expectations.

The purpose of this Task is to create an accessible (e.g., Excel) spreadsheet tool that implements the methodology described in the attached paper by Marshall et al. (2013)[1] for determining whether candidate unstudied PCB mixtures are sufficiently similar to a PCB reference mixture for which a reference point of departure (POD) has been derived.[2]

In addition to the spreadsheet tool, the Contractor shall provide supporting documentation that provides an explanation of the intended purpose of the spreadsheet, instructions for its use, and a detailed description of the methods implemented by the spreadsheet. The EPA WAM and other EPA internal reviewers will provide technical direction as necessary.

The details of the requirements for spreadsheet features will be determined at the task initiation meeting, including the interface design, expected inputs and required outputs. At a minimum, the spreadsheet tool and associated user guide/documentation will be sufficient for determining the similarity of a single candidate PCB mixture to a single reference PCB mixture. Preferably, the package will be able to compare a candidate mixture to a database of reference mixtures and report the reference mixture with the greatest similarity to the candidate mixture. The potential for additional batch processing

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[1] An Empirical Approach to Sufficient Similarity: Combining Exposure Data and Mixtures Toxicology Data. *Risk Analysis* 33(9): 1582-1595

2 It is anticipated that the reference POD used in the mixtures similarity spreadsheet tool will be a value comparable to a benchmark dose (BMD) or extra risk concentration (ERC), or their lower confidence limits, derived by EPA's BMDS or CatReg programs, respectively. However, for the purposes of this task, the value of the POD and the method of its derivation are not relevant. At this point, EPA anticipates that the dose-response modeling needed for the derivation of mixture reference PODs will be performed in software separate from the mixtures similarity estimation tool.

(e.g., the ability to automatically compare multiple mixtures to the database of reference mixtures) and various plotting capabilities will also be discussed at the task initiation meeting.

Task 9a: Draft Spreadsheet Tool

The Contractor shall prepare a draft version of the spreadsheet tool that implements the methodology described in Marshall et al. (2013) for estimating the toxicological similarity of PCB mixtures to reference PCB mixtures for which a reference POD has been derived. For ease of public access, an Excel-based tool is preferred. The feasibility of Excel implementation will be discussed at the task initiation meeting.

At a minimum, the first draft of the spreadsheet tool and associated user guide/documentation will compare a single candidate PCB mixture to a single reference PCB mixture, using a user-defined reference POD and a maximum effective dose (ED_{max}) for establishment of a "similarity bound" (SB) (as described by Marshall et al., 2013) and report the following:

- unweighted and weighted (for congener potency) POD and ED_{max} estimates, with associated standard errors, for both mixtures;
- unweighted and weighted SB estimates derived from the reference mixture ($SB = ED_{max} - POD$);
- the unweighted and weighted Euclidean distance between the PODs for the two mixtures (*d*) that accounts for differences in number of congeners contained in the two mixtures (as described by Marshall et al., 2013), with associated standard errors;
- the upper one-sided 95% confidence limit on the distance between the PODs for the two mixtures (*du*);
- the unweighted and weighted difference between SB and *du* (similarity indicator = $SI = SB - du$); and
- an indication as to whether the unweighted and weighted results suggest that the two mixtures are sufficiently similar ($SI \geq 0$) or not sufficiently similar ($SI < 0$).

Additional drafts of the spreadsheet tool and associated user guide/documentation may be necessary depending on the comments from the EPA WAM on the first draft package and any features decided upon in the task initiation meeting, such as batch processing or plotting features, that were not implemented in the first draft.

Task 9b: Final Spreadsheet Tool

The Contractor shall prepare and deliver a final version of the spreadsheet when final comments from the EPA WAM have been submitted on a version of the spreadsheet tool that contains all features decided upon at the task initiation meeting. The final version shall contain appropriate disclaimers regarding the use of the spreadsheet.

Task 10 (OPTIONAL): Development of Relative Potency Estimates for PCB Congeners

Depending on EPA needs and the decisions made at the Task 9 initiation meeting, the Contractor may be asked to support EPA in the development of relative potency estimates for PCB congeners through the use of existing toxicological data and theoretical methods such as Quantitative Structure Activity Relationship (QSAR) techniques. Should this option be implemented, the EPA WAM and other EPA internal reviewers will provide technical direction as necessary.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Software must be accompanied by a user manual and technical documentation. All deliverables shall be provided in electronic format in Microsoft Word, or Microsoft Excel (or another equally accessible software program), or other format, as indicated.

V. DELIVERABLES AND SCHEDULE

Please note that the amendment of Task 2 and addition of Tasks 9-10 have resulted in significant changes to the schedule of deliverables, as outlined below.

TASK	DELIVERABLES
Task 1. Establish Communication	Completed under WA 1-15
Task 2. Work Plan, Staffing Plan, and QAPP	***Work plan, Staffing Plan, and QAPP for new Tasks 9-10 delivered to EPA WAM and PO within 15 days after issuance of amendment 1 to WA 2-15***
Task 3. Literature Review Products	**Task 3 initiation meeting:** Completed under WA 1-15 **Literature test set screening:** Completed under WA 1-15 **All studies tagged to categories in HERO and literature flow diagram completed:** 105 days following CO approval of WA 2-15 Each update will be due 30 days after notification of a HERO update by EPA
Task 4a & 4b. Preparation of Evidence Tables	**Sample evidence tables for human and animal studies:** Completed under WA 1-15 **Complete evidence tables for human and animal studies:** provided to the EPA WAM as they are completed, but no later

TASK	DELIVERABLES
	than 240 days after EPA approval of the literature review product (Task 3) **Revised evidence tables for human and animal studies:** 30 days after receiving EPA comments on complete evidence tables for human and animal studies Each update will be due 30 days after notification of a HERO update by EPA
Task 5a & 5b. Preparation of Absorption, Distribution, Metabolism, and Excretion (ADME) Inventory Tables and Synthesis Text	**Task 5 initiation meeting:** Completed under WA 1-15 **Sample inventory tables for ADME studies:** 30 days after EPA approval of the literature review product (Task 3) **Complete ADME inventory tables (Task 5a):** 90 days after receiving EPA comments on sample inventory tables **Revised ADME inventory tables (Task 5a):** 30 days after receiving EPA comments on complete ADME inventory tables **Draft synthesis text (Task 5b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 5b):** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 6. Assemble Hazard Identification and/or Dose-Response Conclusions from Other Governmental or International Risk Assessment Bodies	**Draft table:** 120 days after EPA approval of the literature review product (Task 3) **Revised table:** 30 days after receiving EPA comments on draft table
Task 7. Preparation of Synthesis Text to Describe the Evidence for Susceptible Populations and Lifestages	**Task 7 initiation meeting:** 90 days after EPA approval of the literature review product (Task 3)

TASK	DELIVERABLES
	Draft synthesis text: 90 days following Task 7 initiation meeting **Revised synthesis text:** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 8a & 8b. Preparation of Inventory Tables and Synthesis Text to Describe the Evidence for Potential Modes of Action	**Task 8 initiation meeting:** Completed under WA 1-15 **Sample inventory tables for MOA studies:** 90 days after EPA approval of the literature review product (Task 3) **Complete MOA inventory tables (Task 8a):** 90 days after receiving EPA comments on sample inventory tables **Revised MOA inventory tables (Task 8a):** 30 days after receiving EPA comments on complete MOA inventory tables **Draft synthesis text (Task 8b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 8b):** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 9a & 9b. Development of Tool for the Assessment of PCB Mixture Similarity	***Task 9 initiation meeting: 7 days following CO approval of WA 2-15 amendment 1*** ***Draft spreadsheet tool (Task 9a): 30 days after Task 9 initiation meeting*** ***Final spreadsheet tool (Task 9b): 30 days after receiving EPA comments on draft spreadsheet tool***

TASK	DELIVERABLES
Task 10 (OPTIONAL). Development of Relative Potency Estimates for PCB Congeners	*Draft relative potency estimates: 30 days after Task 9 initiation meeting* *Revised relative potency estimates: 30 days after receiving EPA comments on draft relative potency estimates*

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The Contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO, EPA WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the EPA WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Project Officer:

Melissa Revely-Wilson
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Telephone: 703/347-8523 Fax: 703/347-8696

Physical Address:
U.S. Environmental Protection Agency
Two Potomac Yard (North Building)
2733 S. Crystal Drive, RM. 87322, Arlington, VA 22202

X. Work Assignment Manager (WAM)

Geniece M. Lehmann, Ph.D.
Telephone: 919-541-2289
Fax: 919-541-0245
e-mail: Lehmann.Geniece@epa.gov

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Durham, NC 27703

Alternate Work Assignment Manager:

Jeff Gift, Ph.D.
Telephone: 919-541-4828
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e-mail: Gift.Jeff@epa.gov

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Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Preparation of Evidence Tables
	Base X Option Period Number	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 02/01/2016 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$258,699.00	2,853
Total:	$258,699.00	2,853

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 02/05/2016	$258,699.00	2,853
Cumulative Approved:	$258,699.00	2,853

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-2289	
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-0207	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2055	
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	PREPARATION OF EVIDENCE TABLES

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 04/01/2016 To 10/31/2016

Comments:
To amend Task 4 and to add new tasks 11-12

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-2289	
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-0207	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates William Yates (Signature) 3/30/16 (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2055	
	FAX Number:	

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
Amendment 2 to WA 2-15

TITLE: PREPARATION OF EVIDENCE TABLES FOR THE IRIS DRAFT TOXICOLOGICAL REVIEW OF POLYCHLORINATED BIPHENYLS (PCBs): EFFECTS OTHER THAN CANCER (CAS NO. 1336-36-3)

Specify Section & Paragraph SOW: Section A (Assessment Issues and Documents), Subsection 1 (Human Health Assessment Documents)

PERIOD OF PERFORMANCE: CO Approval to 10/31/16

I. PURPOSE

The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of updating the existing draft of the *Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer* (hereinafter the draft Toxicological Review). The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential non-cancer health effects from PCBs by all exposure routes. All applicable Agency guidance and formats should be used in the development of this draft document. ***This amendment provides for continuation and extension of work initiated under Contract EP-C-14-001 WA 2-15.***

II. BACKGROUND

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral RfDs and inhalation RfCs for chronic noncancer health effects, as well as cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

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(Step 2); science consultation with other federal agencies and White House offices (i.e., interagency review) (Step 3); public review and comment and independent expert peer review (i.e., outside EPA) (Step 4); revision of the IRIS assessment and preparation of the IRIS Summary (Step 5); final internal Agency review (i.e., within EPA) and science discussion with other federal agencies and White House offices (i.e., interagency review) (Steps 6A and 6B); and posting the final Toxicological Review and IRIS Summary on the IRIS database (Step 7).

This Performance Work Statement (PWS) addresses Step 1 of the IRIS process for assessment development: development of the draft Toxicological Review. An initial draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer has been written. However, it is now necessary to update the existing draft and to develop materials (literature search strategies, evidence tables, and exposure-response figures) for release to the public for discussion at a problem formulation meeting.

In developing the Toxicological Review, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2000)
- *Use of the Benchmark Dose Approach in Health Risk Assessment* (U.S. EPA, 1995)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)
- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Advances in Inhalation Gas Dosimetry for Derivation of a Reference Concentration (RfC) and Use in Risk Assessment* (U.S. EPA, 2012)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006).

III. STATEMENT OF WORK

This amendment alters the following tasks:

Task 1: Establish Communication

This task was completed under WA 1-15. No further work is expected under this task.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in amended Task 4 and new Tasks 11-12 will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, and that shows assigned personnel by task and the qualifications of the proposed personnel.

The Contractor shall update the existing Quality Assurance Project Plan (QAPP) approved for EPA Contract EP-C-14-001 Work Assignment 2-15 (amendment 1). The Contractor shall submit the updated version to the EPA WAM and Quality Assurance Manager simultaneously with the Work Plan for approval. The Contractor shall not perform any work on amended Task 4 or new Tasks 11-12 until the Work Plan and updated QAPP are reviewed and approved.

The work plan for Task 3 has not changed substantively. The Contractor is not required to submit a new work plan for this unaltered task.

Task 4: Preparation of Evidence Tables

The Contractor shall provide support to EPA in preparing evidence tables that summarize organ-specific toxicity in human studies and animal bioassays. The evidence tables will be generated using the Dose Response Analytical Generator and Organizational Network (DRAGON) Tool.

Task 4a: Human Studies

Evidence tables shall be prepared for non-cancer human data identified in Task 3. ***The studies included in the evidence tables will be determined by EPA following implementation of study quality evaluation protocols.*** The studies shall be sorted by health effect category, with separate tables for each category; studies may be in more than one table. ***Data from each study will be extracted into the DRAGON Tool according to a data extraction protocol developed by EPA and provided to the Contractor.*** The DRAGON Tool will then be used to generate the evidence tables. The Contractor shall initially provide the WAM with sample evidence tables for each health effect category, each populated with data from no more than 10 human studies, providing design and population details, outcome assessment details, exposure measures, and results for each study. The studies included in the sample evidence tables shall be selected to represent a variety of study designs to illustrate the proposed format for display of data from different types of studies (e.g., studies of populations exposed from different sources (occupational, fish consumption, general population exposure), and studies using different epidemiological designs (cross-sectional, longitudinal, case-control)). The WAM will review the sample tables and provide feedback. ***The Contractor shall address EPA comments in a revised version of the sample tables and deliver the revised document to the EPA WAM. This review/revision process may be repeated two or three times to prepare the sample tables for inclusion in the package of preliminary assessment materials released for public comment.***

Following public comment, EPA will provide additional feedback on the sample tables,

which will be used by the Contractor to guide the development of complete human study evidence tables (i.e., containing data from all of the relevant human studies ***selected by EPA from the list developed*** in Task 3). ***These complete human study evidence tables*** will also be provided to the WAM for review. As the complete tables are developed, the Contractor shall periodically consult with the EPA WAM to discuss the table entry format for study types that were not included in the sample tables or whenever the Contractor is unsure about the best format to display data for a given study. EPA will provide the Contractor with comments on the complete human study evidence tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Task 4b: Animal Studies

Concurrent with the development of evidence tables for non-cancer human exposure data in Task 4a, data from subchronic, chronic, reproductive and developmental animal toxicity studies identified in Task 3 shall be summarized in evidence tables sorted by health effect category. ***Again, the studies included in the evidence tables will be determined by EPA following implementation of study quality evaluation protocols.*** Separate sets of tables summarizing information from oral and inhalation exposure studies shall be prepared. ***Data from each study will be extracted into the DRAGON Tool according to a data extraction protocol developed by EPA and provided to the Contractor.*** The DRAGON Tool will then be used to generate the evidence tables. The Contractor shall initially provide the WAM with sample evidence tables for each health effect category, each populated with data from no more than 10 animal studies, providing study design details, outcome assessment details, exposure measures, and results for each study. The studies included in the sample evidence tables shall be selected to represent a variety of study designs to illustrate the proposed format for display of data from different types of studies (e.g., different routes of exposure (oral, inhalation, dermal), different exposure paradigms (subchronic, chronic, multigenerational)). The WAM will review the sample tables and provide feedback. ***The Contractor shall address EPA comments in a revised version of the sample tables and deliver the revised document to the EPA WAM. This review/revision process may be repeated two or three times to prepare the sample tables for inclusion in the package of preliminary assessment materials released for public comment.***

Following public comment, EPA will provide additional feedback on the sample tables, which will be used by the Contractor to guide the development of complete animal study evidence tables (i.e., containing data from all of the relevant animal studies ***selected by EPA from the list developed*** in Task 3). ***These complete animal study evidence tables*** will also be provided to the WAM for review. As the complete tables are developed, the Contractor shall periodically consult with the EPA WAM to discuss the table entry format for study types that were not included in the sample tables or whenever the Contractor is unsure about the best format to display data for a given study. EPA will provide the Contractor with comments on the complete animal study evidence tables. The Contractor shall address EPA comments in a revised version of the tables and deliver the revised document to the EPA WAM. These tables shall be updated as new data become available.

Sample evidence tables were completed under WA 1-15.

The work plan for Tasks 5-10 has not changed substantively. The Contractor is not required to submit a new work plan for these unaltered tasks.

Task 11: Preparation of Health Effect Category Syntheses

Prior to beginning work on Task 11, the Contractor will hold a task initiation meeting with the EPA WAM to discuss the approach, products, and expectations.

The Contractor shall identify, recruit and manage expert scientists to author health effect category synthesis sections. The synthesis sections shall evaluate (1) the available data on endpoints associated with exposure to PCBs, (2) the available data on variations in sensitivity associated with susceptibility, and (3) the available mechanistic data for potential modes of action for each endpoint. The topics of the sections to be authored include the following:

Task 11a: Cardiovascular Toxicology
Task 11b: Liver Toxicology
Task 11c: Nervous System Toxicology (including neurodevelopmental effects)

Details specific to the written sections on each of these topic areas are discussed under Tasks 11a-c below.

Development of each health effect category synthesis section will proceed as described in *Principles and Procedures for Integrated Risk Information System (IRIS) Toxicological Reviews* (hereinafter the IRIS Handbook), which will be provided to the Contractor by the EPA WAM at the task initiation meeting. Briefly, these steps will be followed:

1. Hazard-relevant studies (identified in Task 3) will be organized into a literature inventory and reviewed by the section author to develop a preliminary analysis plan. The preliminary analysis plan outlines the approach that will be taken to focus the review on those studies that are useful as primary studies for hazard identification or dose-response assessment.
2. A hazard-specific study quality evaluation protocol will be developed by the section author in collaboration with the EPA WAM, the PCB assessment team, and the hazard-relevant IRIS disciplinary workgroup. The section author will follow the protocol to evaluate the quality of studies identified in the preliminary analysis plan.
3. A data extraction protocol will be developed by the section author in collaboration with the EPA WAM, the PCB assessment team, and the hazard-relevant IRIS disciplinary workgroup. This protocol will be used to guide the data extraction and evidence table preparation described in Task 4.
4. The health effect category synthesis section will be drafted by the section author according to guidelines presented in the IRIS Handbook and in the *Annotated Outline for IRIS Toxicological Reviews* (hereinafter the IRIS Annotated Outline), which will be provided to the Contractor by the EPA WAM. Draft health effect category synthesis sections will be reviewed by EPA and revised by the section

author in an iterative process intended to maximize the scientific accuracy and transparency of the section as well as its conformance to the guidelines presented in the IRIS Handbook and in the IRIS Annotated Outline and its consistency with other health effect category synthesis sections included in the draft Toxicological Review. There is no set number of iterations this process may take, but it is reasonable to assume that two or three review/revision cycles may occur before EPA acceptance of the final draft health effect category synthesis section.

5. From the data summarized in the health effect category synthesis section, the section author will identify data sets suitable for dose-response analysis and will provide a list of these data sets to the EPA WAM.

Because it is important that each health effect category synthesis section conforms to guidelines set by the IRIS program and that there is consistency in the approaches used across all of the health effect category synthesis sections included in the draft Toxicological Review, it is expected that section authors will communicate regularly with the EPA WAM through weekly teleconferences and additional email and telephone correspondence as necessary. Section authors will also participate (by teleconference) in weekly meetings of the PCB assessment team and in biweekly meetings of the hazard-relevant IRIS disciplinary workgroup. The Contractor shall manage the section authors and ensure that necessary communications occur and that deliverables are provided to the EPA WAM in a timely manner, according to the schedule set at the task initiation meeting.

The EPA assumes primary authorship in the writing process, and contributing authors are listed in the final document as appropriate. EPA will approve (or disapprove) each of the expert authors performing this work within two days of notification of a potential candidate.

Task 11a: Cardiovascular Toxicology

The author of the health effect category synthesis section on cardiovascular effects shall be an expert in the field, demonstrated by qualifications including, but not limited to, education, participation in professional societies, publications in peer reviewed journals, or participation in national or international scientific panels. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11b: Liver Toxicology

The author of the health effect category synthesis section on liver effects shall be an expert in the field, demonstrated by qualifications including, but not limited to, education, participation in professional societies, publications in peer reviewed journals, or participation in national or international scientific panels. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11c: Nervous System Toxicology (including neurodevelopmental effects)

The author of the health effect category synthesis section on nervous system effects shall have a Ph.D., M.D., or equivalent and research experience in neurotoxicology, with preference given for experience in neurodevelopmental toxicology. The ideal author would have at least 10 years of publications on applying neurobehavioral assays, including tests of learning and memory, operant behaviors, and motor function, in rats and/or non-human primates exposed to PCBs or other persistent organic pollutants. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 12 (OPTIONAL): Support in Revising Health Effect Category Syntheses following Various Review Steps

Authors of the health effect category synthesis sections described in Task 11 will provide support to EPA, as directed, in revising those sections following various review steps, including reviews by PCB team members, the IRIS disciplinary workgroups, NCEA and ORD management, EPA Program Offices and Regions, other federal agencies, the Chemical Assessment Advisory Committee (CAAC), and the public. For this task, support to EPA may include the following: summarizing reviewer comments by topic or issue, researching special topics or issues that may be raised by reviewers, making revisions to the health effect category synthesis sections in response to reviewer comments, including integration of information from newly identified studies, and providing technical guidance as needed for the EPA to develop written responses to comments. Additionally, as directed, the section authors will attend (via teleconference) review meetings within ORD and NCEA as well as meetings with EPA Program Offices and Regions and other federal agencies, public science meetings, and meetings with the CAAC. The Contractor shall manage the section authors and ensure that necessary communications occur and that deliverables are provided to the EPA WAM in a timely manner. These activities will generally require a quick turn-around time, and the due dates will be agreed upon by the Contractor and EPA once reviewer comments are available at each step.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word or other format, as indicated. The literature search and electronic copies of the literature shall be provided via an Endnote database and uploaded to HERO.

V. DELIVERABLES AND SCHEDULE

Please note that the amendment of Tasks 2 and 4 and addition of Tasks 11 and 12 have resulted in significant changes to the schedule of deliverables, as outlined below.

TASK	DELIVERABLES
Task 1. Establish Communication	Completed under WA 1-15
Task 2. Work Plan, Staffing Plan, and QAPP	***Work plan, Staffing Plan, and QAPP for revised Task 4 and new Tasks 11-12 delivered to EPA WAM and PO within 15 days after issuance of amendment 2 to WA 2-15***
Task 3. Literature Review Products	**Task 3 initiation meeting:** Completed under WA 1-15 **Literature test set screening:** Completed under WA 1-15 **All studies tagged to categories in HERO and literature flow diagram completed:** 105 days following CO approval of WA 2-15 Each update will be due 30 days after notification of a HERO update by EPA
Task 4a & 4b. Preparation of Evidence Tables	**Sample evidence tables for human and animal studies:** Completed under WA 1-15 ***Revised sample evidence tables for human and animal studies: 30 days after receiving EPA comments on sample evidence tables*** ***Complete evidence tables for human and animal studies: provided to the EPA WAM as they are completed, but no later than 120 days after receiving data extraction protocols from EPA*** **Revised evidence tables for human and animal studies:** 30 days after receiving EPA comments on complete evidence tables for human and animal studies Each update will be due 30 days after notification of a HERO update by EPA
Task 5a & 5b. Preparation of Absorption, Distribution, Metabolism, and Excretion (ADME) Inventory Tables and Synthesis Text	**Task 5 initiation meeting:** Completed under WA 1-15

TASK	DELIVERABLES
	Sample inventory tables for ADME studies: 30 days after EPA approval of the literature review product (Task 3) **Complete ADME inventory tables (Task 5a):** 90 days after receiving EPA comments on sample inventory tables **Revised ADME inventory tables (Task 5a):** 30 days after receiving EPA comments on complete ADME inventory tables **Draft synthesis text (Task 5b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 5b):** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 6. Assemble Hazard Identification and/or Dose-Response Conclusions from Other Governmental or International Risk Assessment Bodies	**Draft table:** 120 days after EPA approval of the literature review product (Task 3) **Revised table:** 30 days after receiving EPA comments on draft table
Task 7. Preparation of Synthesis Text to Describe the Evidence for Susceptible Populations and Lifestages	**Task 7 initiation meeting:** 90 days after EPA approval of the literature review product (Task 3) **Draft synthesis text:** 90 days following Task 7 initiation meeting **Revised synthesis text:** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 8a & 8b. Preparation of Inventory Tables and Synthesis Text to Describe the Evidence for Potential Modes of Action	**Task 8 initiation meeting:** Completed under WA 1-15

TASK	DELIVERABLES
	Sample inventory tables for MOA studies: 90 days after EPA approval of the literature review product (Task 3) **Complete MOA inventory tables (Task 8a):** 90 days after receiving EPA comments on sample inventory tables **Revised MOA inventory tables (Task 8a):** 30 days after receiving EPA comments on complete MOA inventory tables **Draft synthesis text (Task 8b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 8b):** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 9a & 9b. Development of Tool for the Assessment of PCB Mixture Similarity	**Task 9 initiation meeting:** 7 days following CO approval of WA 2-15 amendment 1 **Draft spreadsheet tool (Task 9a):** 30 days after Task 9 initiation meeting **Final spreadsheet tool (Task 9b):** 30 days after receiving EPA comments on draft spreadsheet tool
Task 10 (OPTIONAL). Development of Relative Potency Estimates for PCB Congeners	**Draft relative potency estimates:** 30 days after Task 9 initiation meeting **Revised relative potency estimates:** 30 days after receiving EPA comments on draft relative potency estimates
Task 11a, 11b, & 11c. Preparation of Health Effect Category Syntheses	***List of candidate section authors with biosketches: 21 days following CO approval of WA 2-15 amendment 2*** ***Kickoff conference calls scheduled with section authors: 14 days following EPA approval of candidate section authors***

TASK	DELIVERABLES
	Preliminary analysis plan developed for each section: 60 days after EPA approval of the literature review product (Task 3) ***Study quality evaluation protocol developed for each health effect category: 60 days after EPA approval of the literature review product (Task 3)*** ***Study quality evaluation completed for each section: 60 days after EPA approval of the study quality evaluation protocol*** ***Data extraction protocol developed for each health effect category: 60 days after EPA approval of the study quality evaluation protocol*** ***List of data sets suitable for dose-response analysis from each section: 60 days after completion of the study quality evaluation for the section*** ***Draft synthesis text for each section (iteration 1): 30 days after completion of the study quality evaluation for the section*** ***Draft synthesis text for each section (iteration 2): 15 days after receiving EPA comments on draft synthesis text (iteration 1)*** ***Draft synthesis text for each section (iteration 3): 15 days after receiving EPA comments on draft synthesis text (iteration 2)***
Task 12 (OPTIONAL). Support in Revising Health Effect Category Syntheses following Various Review Steps	***Revised text for each health effect category synthesis section (Task 11): At each review step, revisions will be due 15 days after receiving review comments from EPA WAM. Review steps include (1) review by PCB team and IRIS disciplinary workgroups, (2) NCEA management review, (3) ORD***

TASK	DELIVERABLES
	management review, (4) Agency review, (5) interagency science consultation, (6) public comment, (7) CAAC review, and (8) interagency science discussion.

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The Contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO, EPA WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the EPA WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Project Officer:

Melissa Revely-Wilson
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Telephone: 703/347-8523 Fax: 703/347-8696

Physical Address:
U.S. Environmental Protection Agency
Two Potomac Yard (North Building)
2733 S. Crystal Drive, RM. 87322, Arlington, VA 22202

X. Work Assignment Manager (WAM)

Geniece M. Lehmann, Ph.D.
Telephone: 919-541-2289
Fax: 919-541-0245
e-mail: Lehmann.Geniece@epa.gov

USPS Address:
U.S. Environmental Protection Agency
MD B243-01
Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

Alternate Work Assignment Manager:

Jeff Gift, Ph.D.
Telephone: 919-541-4828
Fax: 919-541-0245
e-mail: Gift.Jeff@epa.gov

USPS Address:
U.S. Environmental Protection Agency
MD B243-01
Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000002

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Preparation of Evidence Tables

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 04/01/2016 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$258,699.00	2853
This Action:	$33,677.00	354
Total:	$292,376.00	3,207

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 03/15/2016	$33,677.00	354
Cumulative Approved:	$292,376.00	3,207

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-2289
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000003

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	PREPARATION OF EVIDENCE TABLES

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 05/01/2016 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2016		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name Geniece Lehmann (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-2289 FAX Number:
Project Officer Name Melissa Revely-Wilson (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name William Yates William Yates (Signature)	4/28/16 (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
Amendment 3 to WA 2-15

TITLE: PREPARATION OF EVIDENCE TABLES FOR THE IRIS DRAFT TOXICOLOGICAL REVIEW OF POLYCHLORINATED BIPHENYLS (PCBs): EFFECTS OTHER THAN CANCER (CAS NO. 1336-36-3)

Specify Section & Paragraph SOW: Section A (Assessment Issues and Documents), Subsection 1 (Human Health Assessment Documents)

PERIOD OF PERFORMANCE: CO Approval to 10/31/16

I. PURPOSE

The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of updating the existing draft of the *Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer* (hereinafter the draft Toxicological Review). The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential non-cancer health effects from PCBs by all exposure routes. All applicable Agency guidance and formats should be used in the development of this draft document. ***This amendment provides for continuation and extension of work initiated under Contract EP-C-14-001 WA 2-15.***

II. BACKGROUND

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral RfDs and inhalation RfCs for chronic noncancer health effects, as well as cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

The IRIS process for assessment development follows the process implemented in May 2009, including enhancements announced in July 2013 (http://www.epa.gov/iris/process.htm): a comprehensive literature search, a public problem formulation meeting, and development of a draft Toxicological Review (Step 1 of the IRIS Assessment Development Process); internal Agency review (i.e., within EPA)

(Step 2); science consultation with other federal agencies and White House offices (i.e., interagency review) (Step 3); public review and comment and independent expert peer review (i.e., outside EPA) (Step 4); revision of the IRIS assessment and preparation of the IRIS Summary (Step 5); final internal Agency review (i.e., within EPA) and science discussion with other federal agencies and White House offices (i.e., interagency review) (Steps 6A and 6B); and posting the final Toxicological Review and IRIS Summary on the IRIS database (Step 7).

This Performance Work Statement (PWS) addresses Step 1 of the IRIS process for assessment development: development of the draft Toxicological Review. An initial draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer has been written. However, it is now necessary to update the existing draft and to develop materials (literature search strategies, evidence tables, and exposure-response figures) for release to the public for discussion at a problem formulation meeting.

In developing the Toxicological Review, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2000)
- *Use of the Benchmark Dose Approach in Health Risk Assessment* (U.S. EPA, 1995)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)
- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Advances in Inhalation Gas Dosimetry for Derivation of a Reference Concentration (RfC) and Use in Risk Assessment* (U.S. EPA, 2012)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
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- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006).

III. STATEMENT OF WORK

This amendment alters the following tasks:

Task 1: Establish Communication

This task was completed under WA 1-15. No further work is expected under this task.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in amended Task 11 will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, and that shows assigned personnel by task and the qualifications of the proposed personnel.

The Quality Assurance Project Plan (QAPP) approved for EPA Contract EP-C-14-001 Work Assignment 2-15 (amendment 2) is not expected to change substantively as a result of amending Task 11. No revision of the QAPP is expected under this amendment.

The work plan for Tasks 3-10 has not changed substantively. The Contractor is not required to submit a new work plan for these unaltered tasks.

Task 11: Preparation of Health Effect Category Syntheses

Prior to beginning work on Task 11, the Contractor will hold a task initiation meeting with the EPA WAM to discuss the approach, products, and expectations.

The Contractor shall identify, recruit and manage expert scientists to author health effect category synthesis sections. The synthesis sections shall evaluate (1) the available data on endpoints associated with exposure to PCBs, (2) the available data on variations in sensitivity associated with susceptibility, and (3) the available mechanistic data for potential modes of action for each endpoint. The topics of the sections to be authored include the following:

Task 11a: Cardiovascular Toxicology
Task 11b: Liver Toxicology
Task 11c: Nervous System Toxicology (including neurodevelopmental effects)
Task 11d: Epidemiology: Neurological Effects (including neurodevelopmental effects)
Task 11e: Epidemiology: Cardiovascular Effects, Endocrine Effects, Gastrointestinal Effects, Hematological Effects, Hepatic Effects, Immunological Effects, Reproductive Effects, and Developmental Effects

Details specific to the written sections on each of these topic areas are discussed under ***Tasks 11a-e*** below.

Development of each health effect category synthesis section will proceed as described in *Principles and Procedures for Integrated Risk Information System (IRIS) Toxicological Reviews* (hereinafter the IRIS Handbook), which will be provided to the Contractor by the EPA WAM at the task initiation meeting. Briefly, these steps will be followed:

1. Hazard-relevant studies (identified in Task 3) will be organized into a literature inventory and reviewed by the section author to develop a preliminary analysis plan. The preliminary analysis plan outlines the approach that will be taken to focus the review on those studies that are useful as primary studies for hazard identification or dose-response assessment.
2. A hazard-specific study quality evaluation protocol will be developed by the section author in collaboration with the EPA WAM, the PCB assessment team,

and the hazard-relevant IRIS disciplinary workgroup. The section author will follow the protocol to evaluate the quality of studies identified in the preliminary analysis plan.

3. A data extraction protocol will be developed by the section author in collaboration with the EPA WAM, the PCB assessment team, and the hazard-relevant IRIS disciplinary workgroup. This protocol will be used to guide the data extraction and evidence table preparation described in Task 4.
4. The health effect category synthesis section will be drafted by the section author according to guidelines presented in the IRIS Handbook and in the *Annotated Outline for IRIS Toxicological Reviews* (hereinafter the IRIS Annotated Outline), which will be provided to the Contractor by the EPA WAM. Draft health effect category synthesis sections will be reviewed by EPA and revised by the section author in an iterative process intended to maximize the scientific accuracy and transparency of the section as well as its conformance to the guidelines presented in the IRIS Handbook and in the IRIS Annotated Outline and its consistency with other health effect category synthesis sections included in the draft Toxicological Review. There is no set number of iterations this process may take, but it is reasonable to assume that two or three review/revision cycles may occur before EPA acceptance of the final draft health effect category synthesis section.
5. From the data summarized in the health effect category synthesis section, the section author will identify data sets suitable for dose-response analysis and will provide a list of these data sets to the EPA WAM.

Because it is important that each health effect category synthesis section conforms to guidelines set by the IRIS program and that there is consistency in the approaches used across all of the health effect category synthesis sections included in the draft Toxicological Review, it is expected that section authors will communicate regularly with the EPA WAM through weekly teleconferences and additional email and telephone correspondence as necessary. Section authors will also participate (by teleconference) in weekly meetings of the PCB assessment team and in biweekly meetings of the hazard-relevant IRIS disciplinary workgroup. The Contractor shall manage the section authors and ensure that necessary communications occur and that deliverables are provided to the EPA WAM in a timely manner, according to the schedule set at the task initiation meeting.

The EPA assumes primary authorship in the writing process, and contributing authors are listed in the final document as appropriate. EPA will approve (or disapprove) each of the expert authors performing this work within two days of notification of a potential candidate.

Task 11a: Cardiovascular Toxicology

The author of the health effect category synthesis section on cardiovascular effects shall be an expert in the field, demonstrated by qualifications including, but not limited to, education, participation in professional societies, publications in peer reviewed journals, or participation in national or international scientific panels. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author

suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11b: Liver Toxicology

The author of the health effect category synthesis section on liver effects shall be an expert in the field, demonstrated by qualifications including, but not limited to, education, participation in professional societies, publications in peer reviewed journals, or participation in national or international scientific panels. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11c: Nervous System Toxicology (including neurodevelopmental effects)

The author of the health effect category synthesis section on nervous system effects shall have a Ph.D., M.D., or equivalent and research experience in neurotoxicology, with preference given for experience in neurodevelopmental toxicology. The ideal author would have at least 10 years of publications on applying neurobehavioral assays, including tests of learning and memory, operant behaviors, and motor function, in rats and/or non-human primates exposed to PCBs or other persistent organic pollutants. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11d: Epidemiology: Neurological Effects (including neurodevelopmental effects)

The author of the health effect category synthesis section on epidemiological evidence for nervous system effects shall have a Ph.D., M.D., or equivalent in epidemiology or a related field with at least 3 years of experience evaluating potential associations between exposures to environmental chemicals and effects on neurodevelopment. The ideal author will have contributed to multiple research articles evaluating the potential for PCB exposure to contribute to neurodevelopmental health outcomes. Preference shall also be given to candidates with the following qualifications:

- ***Contributions to research articles evaluating exposure-response relationships between neurodevelopmental outcomes and non-dioxin-like PCBs***
- ***Analysis of neurodevelopmental data from multiple cohorts with different sources of PCB exposure***
- ***Proven record of productive collaboration on PCB epidemiological research with groups of researchers from institutions outside of that with which the individual is primarily affiliated***
- ***Experience writing or reviewing human health risk assessment-related materials for Federal or state government agencies***

Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11e: Epidemiology: Cardiovascular Effects, Endocrine Effects, Gastrointestinal Effects, Hematological Effects, Hepatic Effects, Immunological Effects, Reproductive Effects, and Developmental Effects

At this time, EPA expects that the draft Toxicological Review will include separate synthesis sections on the epidemiological evidence for each of the following health effect categories (in addition to neurological effects (Task 11d)): cardiovascular effects, endocrine effects, gastrointestinal effects, hematological effects, hepatic effects, immunological effects, reproductive effects, and developmental effects. This list may be expanded or contracted based on the final results of the literature review (Task 3). These sections shall be authored by one or more individuals with a Ph.D., M.D., or equivalent in epidemiology or a related field and at least 3 years of experience evaluating potential associations between exposures to environmental chemicals and effects on human health, with preference given for experience evaluating hematological and hepatic effects. The author(s) of these health effect category synthesis sections shall have expertise demonstrated by qualifications including, but not limited to, education, participation in professional societies, publications in peer reviewed journals, or participation in national or international scientific panels. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 12 (OPTIONAL): Support in Revising Health Effect Category Syntheses following Various Review Steps

Although the description of work to be completed in Task 12 is unchanged with this amendment, the level of effort required to complete Task 12 is connected to amended Task 11; the Contractor shall modify the work plan and budget accordingly.

Authors of the health effect category synthesis sections described in Task 11 will provide support to EPA, as directed, in revising those sections following various review steps, including reviews by PCB team members, the IRIS disciplinary workgroups, NCEA and ORD management, EPA Program Offices and Regions, other federal agencies, the Chemical Assessment Advisory Committee (CAAC), and the public. For this task, support to EPA may include the following: summarizing reviewer comments by topic or issue, researching special topics or issues that may be raised by reviewers, making revisions to the health effect category synthesis sections in response to reviewer comments, including integration of information from newly identified studies, and providing technical guidance as needed for the EPA to develop written responses to comments. Additionally, as directed, the section authors will attend (via teleconference) review meetings within ORD and NCEA as well as meetings with EPA Program Offices and Regions and other federal agencies, public science meetings, and meetings with the CAAC. The Contractor shall manage the section authors and ensure that necessary communications occur and that deliverables are provided to the EPA WAM in a timely manner. These activities will generally require a quick turn-around time, and the due dates will be agreed upon by the Contractor and EPA once reviewer comments are available at each step.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word or other format, as indicated. The literature search and electronic copies of the literature shall be provided via an Endnote database and uploaded to HERO.

V. DELIVERABLES AND SCHEDULE

Please note that the amendment of Task 11 has resulted in changes to the schedule of deliverables, as outlined below.

TASK	DELIVERABLES
Task 1. Establish Communication	Completed under WA 1-15
Task 2. Work Plan, Staffing Plan, and QAPP	***Work plan and Staffing Plan for revised Task 11 delivered to EPA WAM and PO within 15 days after issuance of amendment 3 to WA 2-15*** QAPP completed under WA 2-15 (amendment 2)
Task 3. Literature Review Products	**Task 3 initiation meeting:** Completed under WA 1-15 **Literature test set screening:** Completed under WA 1-15 **All studies tagged to categories in HERO and literature flow diagram completed:** 105 days following CO approval of WA 2-15 Each update will be due 30 days after notification of a HERO update by EPA
Task 4a & 4b. Preparation of Evidence Tables	**Sample evidence tables for human and animal studies:** Completed under WA 1-15 ***Revised sample evidence tables for human and animal studies: 30 days after receiving EPA comments on sample evidence tables*** ***Complete evidence tables for human and animal studies: provided to the EPA WAM as they are completed, but no later***

TASK	DELIVERABLES
	than 120 days after receiving data extraction protocols from EPA **Revised evidence tables for human and animal studies:** 30 days after receiving EPA comments on complete evidence tables for human and animal studies Each update will be due 30 days after notification of a HERO update by EPA
Task 5a & 5b. Preparation of Absorption, Distribution, Metabolism, and Excretion (ADME) Inventory Tables and Synthesis Text	**Task 5 initiation meeting:** Completed under WA 1-15 **Sample inventory tables for ADME studies:** 30 days after EPA approval of the literature review product (Task 3) **Complete ADME inventory tables (Task 5a):** 90 days after receiving EPA comments on sample inventory tables **Revised ADME inventory tables (Task 5a):** 30 days after receiving EPA comments on complete ADME inventory tables **Draft synthesis text (Task 5b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 5b):** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 6. Assemble Hazard Identification and/or Dose-Response Conclusions from Other Governmental or International Risk Assessment Bodies	**Draft table:** 120 days after EPA approval of the literature review product (Task 3) **Revised table:** 30 days after receiving EPA comments on draft table
Task 7. Preparation of Synthesis Text to Describe the Evidence for Susceptible Populations and Lifestages	**Task 7 initiation meeting:** 90 days after EPA approval of the literature review product (Task 3)

TASK	DELIVERABLES
	Draft synthesis text: 90 days following Task 7 initiation meeting **Revised synthesis text:** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 8a & 8b. Preparation of Inventory Tables and Synthesis Text to Describe the Evidence for Potential Modes of Action	**Task 8 initiation meeting:** Completed under WA 1-15 **Sample inventory tables for MOA studies:** 90 days after EPA approval of the literature review product (Task 3) **Complete MOA inventory tables (Task 8a):** 90 days after receiving EPA comments on sample inventory tables **Revised MOA inventory tables (Task 8a):** 30 days after receiving EPA comments on complete MOA inventory tables **Draft synthesis text (Task 8b):** 90 days after receiving EPA comments on sample inventory tables **Revised synthesis text (Task 8b):** 30 days after receiving EPA comments on draft synthesis text Each update will be due 30 days after notification of a HERO update by EPA
Task 9a & 9b. Development of Tool for the Assessment of PCB Mixture Similarity	**Task 9 initiation meeting:** 7 days following CO approval of WA 2-15 amendment 1 **Draft spreadsheet tool (Task 9a):** 30 days after Task 9 initiation meeting **Final spreadsheet tool (Task 9b):** 30 days after receiving EPA comments on draft spreadsheet tool

TASK	DELIVERABLES
Task 10 (OPTIONAL). Development of Relative Potency Estimates for PCB Congeners	**Draft relative potency estimates:** 30 days after Task 9 initiation meeting **Revised relative potency estimates:** 30 days after receiving EPA comments on draft relative potency estimates
Task 11a, 11b, 11c, 11d, & 11e. Preparation of Health Effect Category Syntheses	***List of candidate section authors with biosketches: 21 days following CO approval of WA 2-15 amendment 3*** ***Kickoff conference calls scheduled with section authors: 14 days following EPA approval of candidate section authors*** ***Preliminary analysis plan developed for each section: 60 days after EPA approval of the literature review product (Task 3)*** ***Study quality evaluation protocol developed for each health effect category: 60 days after EPA approval of the literature review product (Task 3)*** ***Study quality evaluation completed for each section: 60 days after EPA approval of the study quality evaluation protocol*** ***Data extraction protocol developed for each health effect category: 60 days after EPA approval of the study quality evaluation protocol*** ***List of data sets suitable for dose-response analysis from each section: 60 days after completion of the study quality evaluation for the section*** ***Draft synthesis text for each section (iteration 1): 30 days after completion of the study quality evaluation for the section*** ***Draft synthesis text for each section (iteration 2): 15 days after receiving EPA comments on draft synthesis text (iteration 1)***

TASK	DELIVERABLES
	Draft synthesis text for each section (iteration 3): 15 days after receiving EPA comments on draft synthesis text (iteration 2)
Task 12 (OPTIONAL). Support in Revising Health Effect Category Syntheses following Various Review Steps	Revised text for each health effect category synthesis section (Task 11): At each review step, revisions will be due 15 days after receiving review comments from EPA WAM. Review steps include (1) review by PCB team and IRIS disciplinary workgroups, (2) NCEA management review, (3) ORD management review, (4) Agency review, (5) interagency science consultation, (6) public comment, (7) CAAC review, and (8) interagency science discussion.

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The Contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO, EPA WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the EPA WAM by telephone

for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Project Officer:

Melissa Revely-Wilson
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Telephone: 703/347-8523 Fax: 703/347-8696

Physical Address:
U.S. Environmental Protection Agency
Two Potomac Yard (North Building)
2733 S. Crystal Drive, RM. 87322, Arlington, VA 22202

X. Work Assignment Manager (WAM)

Geniece M. Lehmann, Ph.D.
Telephone: 919-541-2289
Fax: 919-541-0245
e-mail: Lehmann.Geniece@epa.gov

USPS Address:
U.S. Environmental Protection Agency
MD B243-01
Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

Alternate Work Assignment Manager:

Jeff Gift, Ph.D.
Telephone: 919-541-4828
Fax: 919-541-0245
e-mail: Gift.Jeff@epa.gov

USPS Address:
U.S. Environmental Protection Agency

MD B243-01
Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000003

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Preparation of Evidence Tables

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 05/01/2016 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$292,376.00	3207
This Action:	$183,970.00	1,342
Total:	$476,346.00	4,549

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 04/20/2016	$183,970.00	1,342
Cumulative Approved:	$476,346.00	4,549

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2289 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000003

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	PREPARATION OF EVIDENCE TABLES

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 05/01/2016 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$476,346.00	4549
This Action:	$124,250.00	844
Total:	$600,596.00	5,393

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 05/23/2016	$124,250.00	844
Cumulative Approved:	$600,596.00	5,393

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-2289 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000004

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	PREPARATION OF EVIDENCE TABLES

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/08/2016 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee — LOE:

Cumulative Approved: — Cost/Fee — LOE:

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-2289	
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number: 919-541-0207	
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates William Yates (Signature) 6-9-2016 (Date)	Branch/Mail Code:	
	Phone Number: 513-487-2055	
	FAX Number:	

Work Assignment Form. (WebForms v1.0)

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
Amendment 4 to WA 2-15

TITLE: PREPARATION OF EVIDENCE TABLES FOR THE IRIS DRAFT TOXICOLOGICAL REVIEW OF POLYCHLORINATED BIPHENYLS (PCBs): EFFECTS OTHER THAN CANCER (CAS NO. 1336-36-3)

Specify Section & Paragraph SOW: Section A (Assessment Issues and Documents), Subsection 1 (Human Health Assessment Documents)

PERIOD OF PERFORMANCE: CO Approval to 10/31/16

I. PURPOSE

The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of updating the existing draft of the *Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer* (hereinafter the draft Toxicological Review). The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential non-cancer health effects from PCBs by all exposure routes. All applicable Agency guidance and formats should be used in the development of this draft document. ***This amendment provides for continuation and extension of work initiated under Contract EP-C-14-001 WA 2-15.***

II. BACKGROUND

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral RfDs and inhalation RfCs for chronic noncancer health effects, as well as cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

The IRIS process for assessment development follows the process implemented in May 2009, including enhancements announced in July 2013 (http://www.epa.gov/iris/process.htm): a comprehensive literature search, a public problem formulation meeting, and development of a draft Toxicological Review (Step 1 of the IRIS Assessment Development Process); internal Agency review (i.e., within EPA)

(Step 2); science consultation with other federal agencies and White House offices (i.e., interagency review) (Step 3); public review and comment and independent expert peer review (i.e., outside EPA) (Step 4); revision of the IRIS assessment and preparation of the IRIS Summary (Step 5); final internal Agency review (i.e., within EPA) and science discussion with other federal agencies and White House offices (i.e., interagency review) (Steps 6A and 6B); and posting the final Toxicological Review and IRIS Summary on the IRIS database (Step 7).

This Performance Work Statement (PWS) addresses Step 1 of the IRIS process for assessment development: development of the draft Toxicological Review. An initial draft of the Toxicological Review of Polychlorinated Biphenyls (PCBs): Effects Other Than Cancer has been written. However, it is now necessary to update the existing draft and to develop materials (literature search strategies, evidence tables, and exposure-response figures) for release to the public for discussion at a problem formulation meeting.

In developing the Toxicological Review, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Benchmark Dose Technical Guidance Document* (U.S. EPA, 2000)
- *Use of the Benchmark Dose Approach in Health Risk Assessment* (U.S. EPA, 1995)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)
- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Advances in Inhalation Gas Dosimetry for Derivation of a Reference Concentration (RfC) and Use in Risk Assessment* (U.S. EPA, 2012)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006).

III. STATEMENT OF WORK

This amendment alters the following tasks:

Task 1: Establish Communication

This task was completed under WA 1-15. No further work is expected under this task.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in amended Task 11 will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, and that shows assigned personnel by task and the qualifications of the proposed personnel.

The Quality Assurance Project Plan (QAPP) approved for EPA Contract EP-C-14-001 Work Assignment 2-15 (amendment 2) is not expected to change substantively as a result of amending Task 11. No revision of the QAPP is expected under this amendment.

The work plan for Tasks 3-10 has not changed substantively. The Contractor is not required to submit a new work plan for these unaltered tasks.

Task 11: Preparation of Health Effect Category Syntheses

Prior to beginning work on Task 11, the Contractor will hold a task initiation meeting with the EPA WAM to discuss the approach, products, and expectations.

The Contractor shall identify, recruit and manage expert scientists to author health effect category synthesis sections. The synthesis sections shall evaluate (1) the available data on endpoints associated with exposure to PCBs, (2) the available data on variations in sensitivity associated with susceptibility, and (3) the available mechanistic data for potential modes of action for each endpoint. The topics of the sections to be authored include the following:

Task 11a: Toxicology: Neurological Effects (including neurodevelopmental effects)
Task 11b: Toxicology: Cardiovascular Effects, Dermal & Ocular Effects, Endocrine Effects, Gastrointestinal Effects, Hematological Effects, Hepatic Effects, Immunological Effects, Metabolic Effects, Reproductive Effects, and Developmental Effects
Task 11c: Epidemiology: Neurological Effects (including neurodevelopmental effects)
Task 11d: Epidemiology: Cardiovascular Effects, Dermal & Ocular Effects, Endocrine Effects, Gastrointestinal Effects, Hematological Effects, Hepatic Effects, Immunological Effects, Metabolic Effects, Reproductive Effects, and Developmental Effects

Details specific to the written sections on each of these topic areas are discussed under ***Tasks 11a-d*** below.

Development of each health effect category synthesis section will proceed as described in *Principles and Procedures for Integrated Risk Information System (IRIS) Toxicological Reviews* (hereinafter the IRIS Handbook), which will be provided to the Contractor by the EPA WAM at the task initiation meeting. Briefly, these steps will be followed:

1. Hazard-relevant studies (identified in Task 3) will be organized into a literature inventory and reviewed by the section author to develop a preliminary analysis plan. The preliminary analysis plan outlines the approach that will be taken to

focus the review on those studies that are useful as primary studies for hazard identification or dose-response assessment.

2. A hazard-specific study quality evaluation protocol will be developed by the section author in collaboration with the EPA WAM, the PCB assessment team, and the hazard-relevant IRIS disciplinary workgroup. The section author will follow the protocol to evaluate the quality of studies identified in the preliminary analysis plan.
3. A data extraction protocol will be developed by the section author in collaboration with the EPA WAM, the PCB assessment team, and the hazard-relevant IRIS disciplinary workgroup. This protocol will be used to guide the data extraction and evidence table preparation described in Task 4.
4. The health effect category synthesis section will be drafted by the section author according to guidelines presented in the IRIS Handbook and in the *Annotated Outline for IRIS Toxicological Reviews* (hereinafter the IRIS Annotated Outline), which will be provided to the Contractor by the EPA WAM. Draft health effect category synthesis sections will be reviewed by EPA and revised by the section author in an iterative process intended to maximize the scientific accuracy and transparency of the section as well as its conformance to the guidelines presented in the IRIS Handbook and in the IRIS Annotated Outline and its consistency with other health effect category synthesis sections included in the draft Toxicological Review. There is no set number of iterations this process may take, but it is reasonable to assume that two or three review/revision cycles may occur before EPA acceptance of the final draft health effect category synthesis section.
5. From the data summarized in the health effect category synthesis section, the section author will identify data sets suitable for dose-response analysis and will provide a list of these data sets to the EPA WAM.

Because it is important that each health effect category synthesis section conforms to guidelines set by the IRIS program and that there is consistency in the approaches used across all of the health effect category synthesis sections included in the draft Toxicological Review, it is expected that section authors will communicate regularly with the EPA WAM through weekly teleconferences and additional email and telephone correspondence as necessary. Section authors will also participate (by teleconference) in weekly meetings of the PCB assessment team and in biweekly meetings of the hazard-relevant IRIS disciplinary workgroup. The Contractor shall manage the section authors and ensure that necessary communications occur and that deliverables are provided to the EPA WAM in a timely manner, according to the schedule set at the task initiation meeting.

The EPA assumes primary authorship in the writing process, and contributing authors are listed in the final document as appropriate. EPA will approve (or disapprove) each of the expert authors performing this work within two days of notification of a potential candidate.

Task 11a: Toxicology: Neurological Effects (including neurodevelopmental effects)

The author of the health effect category synthesis section on nervous system effects shall have a Ph.D., M.D., or equivalent and research experience in neurotoxicology,

with preference given for experience in neurodevelopmental toxicology. The ideal author would have at least 10 years of publications on applying neurobehavioral assays, including tests of learning and memory, operant behaviors, and motor function, in rats and/or non-human primates exposed to PCBs or other persistent organic pollutants. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11b: Toxicology: Cardiovascular Effects, Dermal & Ocular Effects, Endocrine Effects, Gastrointestinal Effects, Hematological Effects, Hepatic Effects, Immunological Effects, Metabolic Effects, Reproductive Effects, and Developmental Effects

At this time, EPA expects that the draft Toxicological Review will include separate synthesis sections on the toxicological evidence for each of the following health effect categories (in addition to neurological effects (Task 11a)): cardiovascular effects, dermal & ocular effects, endocrine effects, gastrointestinal effects, hematological effects, hepatic effects, immunological effects, metabolic effects, reproductive effects, and developmental effects. This list may be expanded or contracted based on the final results of the literature review (Task 3). These sections shall be authored by one or more experts in the field of toxicology, demonstrated by qualifications including, but not limited to, education (i.e., a Ph.D., M.D., or equivalent in toxicology or a related field), participation in professional societies, publications in peer reviewed journals, or participation in national or international scientific panels. Preference will be given to candidates with experience evaluating toxicological effects of exposure to PCBs. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the authors suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11c: Epidemiology: Neurological Effects (including neurodevelopmental effects)

The author of the health effect category synthesis section on epidemiological evidence for nervous system effects shall have a Ph.D., M.D., or equivalent in epidemiology or a related field with at least 3 years of experience evaluating potential associations between exposures to environmental chemicals and effects on neurodevelopment. The ideal author will have contributed to multiple research articles evaluating the potential for PCB exposure to contribute to neurodevelopmental health outcomes. Preference shall also be given to candidates with the following qualifications:

- *Contributions to research articles evaluating exposure-response relationships between neurodevelopmental outcomes and non-dioxin-like PCBs*
- *Analysis of neurodevelopmental data from multiple cohorts with different sources of PCB exposure*
- *Proven record of productive collaboration on PCB epidemiological research with groups of researchers from institutions outside of that with which the individual is primarily affiliated*
- *Experience writing or reviewing human health risk assessment-related materials for Federal or state government agencies*

Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 11d: Epidemiology: Cardiovascular Effects, Dermal & Ocular Effects, Endocrine Effects, Gastrointestinal Effects, Hematological Effects, Hepatic Effects, Immunological Effects, Metabolic Effects, Reproductive Effects, and Developmental Effects

At this time, EPA expects that the draft Toxicological Review will include separate synthesis sections on the epidemiological evidence for each of the following health effect categories (in addition to neurological effects (Task 11c)): cardiovascular effects, dermal & ocular effects, endocrine effects, gastrointestinal effects, hematological effects, hepatic effects, immunological effects, metabolic effects, reproductive effects, and developmental effects. This list may be expanded or contracted based on the final results of the literature review (Task 3). These sections shall be authored by one or more individuals with a Ph.D., M.D., or equivalent in epidemiology or a related field and at least 3 years of experience evaluating potential associations between exposures to environmental chemicals and effects on human health, with preference given for experience evaluating health effects of PCBs or other persistent organic pollutants. The author(s) of these health effect category synthesis sections shall have expertise demonstrated by qualifications including, but not limited to, education, participation in professional societies, publications in peer reviewed journals, or participation in national or international scientific panels. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the author suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Task 12 (OPTIONAL): Support in Revising Health Effect Category Syntheses following Various Review Steps

Although the description of work to be completed in Task 12 is unchanged with this amendment, the level of effort required to complete Task 12 is connected to amended Task 11; the Contractor shall modify the work plan and budget accordingly.

Authors of the health effect category synthesis sections described in Task 11 will provide support to EPA, as directed, in revising those sections following various review steps, including reviews by PCB team members, the IRIS disciplinary workgroups, NCEA and ORD management, EPA Program Offices and Regions, other federal agencies, the Chemical Assessment Advisory Committee (CAAC), and the public. For this task, support to EPA may include the following: summarizing reviewer comments by topic or issue, researching special topics or issues that may be raised by reviewers, making revisions to the health effect category synthesis sections in response to reviewer comments, including integration of information from newly identified studies, and providing technical guidance as needed for the EPA to develop written responses to comments. Additionally, as directed, the section authors will attend (via teleconference) review meetings within ORD and NCEA as well as meetings with EPA Program Offices and Regions and other federal agencies, public science meetings, and meetings with the

CAAC. The Contractor shall manage the section authors and ensure that necessary communications occur and that deliverables are provided to the EPA WAM in a timely manner. These activities will generally require a quick turn-around time, and the due dates will be agreed upon by the Contractor and EPA once reviewer comments are available at each step.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word or other format, as indicated. The literature search and electronic copies of the literature shall be provided via an Endnote database and uploaded to HERO.

V. DELIVERABLES AND SCHEDULE

Please note that the amendment of Task 11 has resulted in changes to the schedule of deliverables, as outlined below.

TASK	DELIVERABLES
Task 1. Establish Communication	Completed under WA 1-15
Task 2. Work Plan, Staffing Plan, and QAPP	***Work plan and Staffing Plan for revised Task 11 delivered to EPA WAM and PO within 15 days after issuance of amendment 4 to WA 2-15*** QAPP completed under WA 2-15 (amendment 2)
Task 11a, 11b, 11c, & 11d. Preparation of Health Effect Category Syntheses	***List of candidate section authors with biosketches: 21 days following CO approval of WA 2-15 amendment 4*** ***Kickoff conference calls scheduled with section authors: 14 days following EPA approval of candidate section authors*** ***Preliminary analysis plan developed for each section: 60 days after EPA approval of the literature review product (Task 3)*** ***Study quality evaluation protocol developed for each health effect category: 60 days after EPA approval of the literature review product (Task 3)***

TASK	DELIVERABLES
	Study quality evaluation completed for each section: 60 days after EPA approval of the study quality evaluation protocol ***Data extraction protocol developed for each health effect category: 60 days after EPA approval of the study quality evaluation protocol*** ***List of data sets suitable for dose-response analysis from each section: 60 days after completion of the study quality evaluation for the section*** ***Draft synthesis text for each section (iteration 1): 30 days after completion of the study quality evaluation for the section*** ***Draft synthesis text for each section (iteration 2): 15 days after receiving EPA comments on draft synthesis text (iteration 1)*** ***Draft synthesis text for each section (iteration 3): 15 days after receiving EPA comments on draft synthesis text (iteration 2)***
Task 12 (OPTIONAL). Support in Revising Health Effect Category Syntheses following Various Review Steps	Revised text for each health effect category synthesis section (Task 11): At each review step, revisions will be due 15 days after receiving review comments from EPA WAM. Review steps include (1) review by PCB team and IRIS disciplinary workgroups, (2) NCEA management review, (3) ORD management review, (4) Agency review, (5) interagency science consultation, (6) public comment, (7) CAAC review, and (8) interagency science discussion.

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The Contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO, EPA WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The Contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the EPA WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Project Officer:

Melissa Revely-Wilson
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Telephone: 703/347-8523 Fax: 703/347-8696

Physical Address:
U.S. Environmental Protection Agency
Two Potomac Yard (North Building)
2733 S. Crystal Drive, RM. 87322, Arlington, VA 22202

X. Work Assignment Manager (WAM)

Geniece M. Lehmann, Ph.D.
Telephone: 919-541-2289
Fax: 919-541-0245

e-mail: Lehmann.Geniece@epa.gov

USPS Address:
U.S. Environmental Protection Agency
MD B243-01
Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

Alternate Work Assignment Manager:

Jeff Gift, Ph.D.
Telephone: 919-541-4828
Fax: 919-541-0245
e-mail: Gift.Jeff@epa.gov

USPS Address:
U.S. Environmental Protection Agency
MD B243-01
Research Triangle Park, NC 27711

Other Delivery Address:
U.S. Environmental Protection Agency
MD B243-01
4930 Old Page Rd.
Durham, NC 27703

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-15

☐ Other ☒ Amendment Number: 000004

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Preparation of Evidence Tables

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 06/08/2016 To 10/31/2016

Comments:
Please approve the work plan at this time with a not-to-exceed (NTE) amount of $100,000.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*) ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$600,596.00	5393
This Action:	$295,988.00	2,053
Total:	$896,584.00	7,446

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 06/29/2016	$295,988.00	2,053
Cumulative Approved:	$896,584.00	7,446

Work Assignment Manager Name: Geniece Lehmann (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-2289
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2055
	FAX Number:	

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-17

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Scientific and Technical Produ
	Base Option Period Number 2	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A1. Human Health Assessment Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/12/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Taukecha Cunningham (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0294 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-17

TITLE: Scientific and Technical Product Development for NCEA

Specify Section & Paragraph SOW: A1. Human Health Assessment Documents

PERIOD of PERFORMANCE: CO approval through October 31, 2016

I. PURPOSE

This work assignment is a follow-on to work performed in the Base Period under Work Assignment # 1-17. The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA) for document production activities which include technical editing, word processing, and graphics support.

II. BACKGROUND

The National Center for Environmental Assessment (NCEA), a major component of EPA's Office of Research and Development (ORD), with headquarters in Washington, DC, is EPA's national resource center for human health and ecological risk assessment. NCEA occupies a critical position in ORD between researchers in other parts of ORD and outside of EPA who are generating new findings and data, and the regulators in EPA's program offices and regions who must make regulatory, enforcement, and remedial action decisions. NCEA prepares technical reports and assessments that integrate and evaluate the most up-to-date research and serve as major elements of the science foundation supporting EPA policies. As a result, NCEA plays an important role as a consultant to EPA programs and regions on the use of science in environmental decision making and also influences the direction of environmental research.

III. STATEMENT OF WORK

The purpose of this work assignment is to provide technical editing and/or revisions of approximately 6 documents. For the purpose of developing the cost for the work plan, the contractor can assume that each document is approximately 150 pages.

Task 1: Establish Communication

Within 3 days of the start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The WAM will submit the documents to be edited via a Contract Service Form. This form will be used as instructions to the contractor and will be submitted with each document. Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel.

Technical/Nontechnical Writing and Technical Editing

The contractor shall ensure the quality of NCEA products by providing technical writing and editorial services for ORD special reports, technical documents, and other written materials. The contractor shall use the Editing Guidelines/Procedures specified by the WAM (*Handbook for Preparing NCEA Documents,* IRIS template, or other specific guidelines, e.g., journal manuscripts would have their own format).

The contractor shall provide an editor (scientist) with an excellent command of the English language, grammar, and spelling. The editor shall be experienced in scientific and technical writing.

The contractor shall perform various tasks in support of EPA research and development efforts including the following:

• Write or rewrite scientific/technical material for scientific and technical audiences. The original document or manuscript provided generally will have been written by specialists in the subject. The contractor must be familiar with scientific and technical terminology (e.g., risk assessment, ecology, solid and hazardous waste, incineration and combustion, etc.) and shall revise the document to the point that it can be easily read and comprehended by the technical community.

• Write or rewrite scientific/technical material in terminology familiar to educated laymen. Rewriting shall include assessing previously written material for unity, coherence, and appropriateness of language and style for the intended audience.

• The contractor shall edit documents electronically using the track edit feature or perform a hard copy edit (legible, handwritten corrections in red ink on the hard copy of the document) when requested.

• The contractor shall closely read the manuscript to ensure correct grammar, spelling, and punctuation; consistency of capitalization, spelling, and hyphenation; agreement of verbs and subjects; check materials, especially tables, figures, units of measure, headings, etc. for consistency of style and format; check placement of tables and figures; and many other details of style.

• The contractor shall rewrite or reorganize sentences, paragraphs, sections, etc.; verify the accuracy of technical terminology, assess illustrations to determine clarity of presentation, need for redrawing, retouching, etc.; cross-check information in the text to tables, figures, appendices, and references and correct apparent disagreements; correct inconsistencies in format and style; assure consistency and accuracy of chemical formulae, mathematical expressions, tables, figures, equations, chemical and biological names; provide a list of queries regarding any questions or concerns with reference to their location in the document; rewrite as needed to ensure clarity throughout the document and that tone and complexity of the document are appropriate for the intended audience.

• The contractor shall check references to ensure that all references cited in the text and only those references have been included in the reference section of the document and verify the accuracy, completeness, and adherence to established format. The contractor will add links for references that are in the HERO library.

• The contractor must be conscientious, attentive to detail, and able to work under considerable pressure (e.g., ability to manage multiple projects that have very short deadlines).

Word Processing/Graphics

The material provided to the contractor shall be provided in a variety of formats including, but not limited to, handwritten form or typed rough draft. Documents may contain chemical formulae, mathematical expressions, tables, figures, equations, chemical and biological names, and other terminology specific to scientific/technical documents. The contractor shall operate IBM-compatible PCs and associated peripheral devices (printers, scanners) and provide support for software applications such as Microsoft Office Suite, Word Perfect, or other applications introduced as EPA standard.

• The contractor shall become familiar with NCEA formatting standards and make any necessary revisions and/or formatting corrections to documents. The contractor shall use features of MS Word as needed (e.g., indexing, generated Table of Contents, text art, etc.).

• The contractor shall plan layout and typing of complicated statistical tables and equations to maintain uniformity and balance in spacing (equations will be typed using the current version of MS Word's Equation Editor). The contractor must be conscientious and attentive to detail.

• The contractor shall prepare NCEA products for loading onto our web sites including but not limited to the use of Adobe Acrobat to convert products (documents, posters, and presentations) to 508 compliant pdf format. The contractor shall prepare press quality pdf files (with embedded fonts and CMYK colors) for printing when needed and verify that settings are correct and that all files have been included.

• The contractor must have excellent proofreading skills.

All word processed material shall be proofread. The contractor shall compare corrections made by the word processor with those requested by the author for accuracy and return the document for further correction as needed.

• Using standard graphics software (e.g., Illustrator, InDesign), the contractor shall create or revise figures as needed.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, PDFs, InDesign).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of WA
Task 2. Work Plan and Staffing Plan	15 days after award

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the WAM at the initiation of the work assignment. Standard reporting requirements of the contract apply for active/completed projects.

IX. OTHER REQUIREMENTS

The WAM will have oversight on all materials developed by the contractor. The primary communication mechanism between the WAM and the contractor shall be email.

In cases where the work to be performed is of a highly scientific or technical nature or requires consultation or interactions, it may be more expedient for the contractor to interact directly with members of the scientific/technical staff.

X. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this WA shall be sent to the PO.

Work Assignment Manager:

Taukecha Cunningham
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Telephone: 703-347-0294; Fax: 703: 703-347-8691
Cunningham.taukecha@epa.gov

Physical Address:
Two Potomac Yard (North Building) N-7341
2733 S. Crystal Drive,
Arlington, VA 22202

Alternate Work Assignment Manager:

Terri Konoza
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Telephone: 703-347-8672; Fax: 703-347-8691
konoza.terri@epa.gov

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-17

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Scientific and Technical Produ
	Base Option Period Number 2	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A1. Human Health Assessment Documents

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/12/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016	Cost/Fee:	$0.00	LOE: 0
This Action:		$62,950.00	618
Total:		$62,070.00	618

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 12/02/2016	Cost/Fee	$62,950.00	LOE: 618
Cumulative Approved:	Cost/Fee	$62,070.00	LOE: 618

Work Assignment Manager Name: Taukecha Cunningham (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-0294 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-18

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Toxicological Review of Inorga

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Assessment Issues and Documents 1. Human Health As

Purpose:
- ☒ Work Assignment
- ☐ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2016		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

	Cost/Fee:	LOE:
Contractor WP Dated:		
Cumulative Approved:		

Work Assignment Manager Name: Janice S. Lee (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-9458 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-18 – Option Year 2

TITLE: Draft Development of the Toxicological Review of Inorganic Arsenic (cancer and non-cancer effects)

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents

PERIOD OF PERFORMANCE: *11/01/2015 thru 10/31/2016*

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), for development of a human health risk assessment for toxicological effects of oral exposure to inorganic arsenic (iAs). The development of the iAs human health risk assessment will include the draft development of evidence tables and draft development of a human health risk assessment of both cancer and non-cancer effects of oral exposure to iAs, including potential use of probabilistic risk assessment methodology.

II. BACKGROUND

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides human health toxicity values for chronic noncancer health effects, as well as cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

The IRIS process for assessment development follows the process implemented in May 2009 (http://www.epa.gov /iris/process.htm), which consists of: a comprehensive literature search; a call for technical information from the public via a Federal Register notice; development of a draft Toxicological Review (Step 1 of the IRIS Assessment Development Process); internal Agency review (i.e., within EPA) (Step 2); science consultation with other federal agencies and White House offices (i.e., interagency review) (Step 3); external peer review (i.e., outside EPA) and public review and comment (Step 4); revision of the IRIS assessment and preparation of the IRIS Summary (Step 5); final internal Agency review (i.e., within EPA) and science discussion with other federal agencies and White House offices (i.e., interagency review) (Steps 6A and 6B); and posting the final Toxicological Review and IRIS Summary on the IRIS database (Step 7).

This PWS addresses Step 3 of the IRIS process for assessment development: development of the draft Toxicological Review. The overall goal of the iAs human health risk assessment is to provide scientifically-

defensible reasoning for the choice of critical cancer and non-cancer effects due to oral exposure of iAs exposure, along with the literature and principal study(ies) that best represent and support that choice.

The Contractor shall extract data and develop evidence tables for the major toxicological effects for the draft Toxicological Review. EPA will identify the studies to be included in these tables as well as provide the table structure for this task. The Contractor shall also help draft sections of the iAs human health risk assessment. The Contractor shall manage the drafting process, including identifying and selecting expert writers as well as managing the drafting process. The Contractor shall also provide options for the probabilistic risk assessment of effects resulting from iAs exposure. The Work Assignment Manager (WAM) and other EPA internal reviewers will provide technical direction as necessary.

In developing the Toxicological Review, the Contractor shall follow, as applicable, the following EPA guidance documents:

- *A Review of the Reference Dose and Reference Concentration Processes* (U.S. EPA, 2002)
- *Guidelines for Neurotoxicity Risk Assessment* (U.S. EPA, 1998)
- *Guidelines for Reproductive Toxicity Risk Assessment* (U.S. EPA, 1996)
- *Guidelines for Developmental Toxicity Risk Assessment* (U.S. EPA, 1991)
- *Guidelines for Mutagenicity Risk Assessment* (U.S. EPA, 1986)
- *Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry* (U.S. EPA, 1994)
- *Recommendations for and Documentation of Biological Values for Use in Risk Assessment* (U.S. EPA, 1988)
- *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986)
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 2000)
- *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006)

III. STATEMENT OF WORK

A. Objective

The objective of this Work Assignment (WA) is to provide technical support for the development of the Toxicological Review of Inorganic Arsenic (cancer and non-cancer effects). Specific requirements for the proposed work are provided below and in guidance documents referenced in this Performance Work Statement (PWS).

B. Specific Requirements

The use of "redline" versions of the documents shall be employed throughout the process. All documents shall be technically edited for format and grammar before being submitted to the EPA Work Assignment Manager (WAM).

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; and "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data.*"

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3: Efforts related to Stressor Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in responding to reviewer comments on stressor considerations for inorganic arsenic. All applicable Agency guidance and formats should be used in preparing response to reviewer comments. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

3.1 Stressor Considerations – Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents related to stressor considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents related to stressor considerations
Written responses to comment on documents related to stressor considerations (based upon technical direction)

Task 4: Efforts related to Exposure Pathway Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in in responding to reviewer comments on exposure pathway considerations for inorganic arsenic, which may include revising exposure pathway models. All applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

4.1 Exposure Pathway Model Considerations – Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents related to exposure pathway considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents/models related to exposure pathway considerations
Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)

Task 5: Efforts related to Receptor Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in developing an IRIS toxicological review for inorganic arsenic. The toxicological review shall characterize potential receptors of inorganic arsenic exposure. Receptors are populations, including life stages, which are exposed to the stressor. Potential human receptors include the general population, susceptible populations (e.g., pre-existing diseases, smoking, drinking, lifestages, etc.), and exposure during particular periods of development. This document will implement recommendations made by National Research Council in "Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic – Interim Report" with respect to consideration of sources of exposure. In addition, all applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

5.1 Receptor Considerations - Sensitivity analyses: The Contractor shall develop sensitivity analyses to determine how receptor considerations impact dose-response analyses for inorganic arsenic. Receptor considerations for sensitivity analyses shall include, but are not limited to, smoking synergism size effect for health effects associated with inorganic arsenic. Data required to perform sensitivity analyses shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database.

Deliverable:
Sensitivity analyses describing the impact of receptor considerations on dose-response analyses

5.2 Receptor Considerations - Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents related to receptor considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents/analyses related to receptor considerations

Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)

Task 6: Efforts related to Endpoint Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in developing an IRIS toxicological review for inorganic arsenic. The toxicological review shall characterize potential endpoints of inorganic arsenic exposure. Endpoints are measures of the effects of exposure to inorganic arsenic. Potential endpoints associated with exposure to inorganic arsenic include both cancer and non-cancer health effects. Consideration of health effects in the IRIS toxicological review of inorganic arsenic will implement recommendations made by National Research Council in "Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic – Interim Report" with respect to. In addition, all applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

6.1 Endpoint Synthesis Text: The Contractor shall identify, recruit and manage expert scientists to author synthesis sections. The synthesis sections shall evaluate the available data on endpoints associated with exposure to inorganic arsenic, including data presented in endpoint evidence tables. Where possible, the Contractor shall develop meta-analyses for endpoints as recommended by the National Research Council. These meta-analyses shall be reviewed by the identified experts as part of developing the synthesis sections. The synthesis sections shall conform to the style and the form of the revised IRIS format, generally. The Contractor shall be responsible for ensuring necessary communication from the EPA reaches the expert authors so that technical clarification can be offered and interaction between authors can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

The EPA assumes primary authorship in the writing process and contributing authors are listed in the final document as appropriate. The expert writers will receive authorship credit on the IRIS Toxicological Review of Inorganic Arsenic and therefore will be considered responsible for the scientific content. EPA will review the qualifications of the expert authors performing this work within two days of notification of a potential candidate to ensure the potential candidates meet the criteria to perform this task. Specific responsibilities for this sub-task include:

In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this statement of work.

Deliverables:
Endpoint synthesis section, including where possible meta-analyses, delivered by deadlines noted in SOW

6.2 Endpoint Qualitative Mode of Action Syntheses: The Contractor shall assist EPA in developing qualitative mode of action syntheses. These syntheses will evaluate the available mechanistic data for several potential modes of action of inorganic arsenic. Potential modes of action may include, but are not limited to, apoptosis and cellular proliferation, activation of reactive oxygen species, impaired immune function, and changes in gene expression and/or regulation. The mode of action syntheses will inform the endpoint causal determination.

6.2.1 Endpoint Qualitative Mode of Action Syntheses Summary Tables: The Contractor shall prepare tables summarizing the available evidence considered during qualitative evaluation of potential modes of action for inorganic arsenic. At a minimum, these tables should include the relevant bibliographic information, description of study design/quality, reported effects of iAs exposure, and dose-response information. These tables shall be updated as new data become available. The data used to create these evidence tables shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database.

Deliverable:
Summary tables on potential modes of action, including updates to incorporate new data

6.2.2 Endpoint Qualitative Mode of Action Synthesis: The Contractor shall develop synthesis text qualitatively describing potential modes of action for inorganic arsenic. The synthesis sections shall evaluate the available mechanistic data on inorganic arsenic associated with exposure to inorganic arsenic, including data presented in endpoint qualitative mode of action summary tables. The synthesis sections shall conform to the style and the form of the revised IRIS format, generally. The Contractor shall be responsible for ensuring communication between the EPA and the expert authors so that technical clarification can be offered and interaction between authors can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

Deliverable:
Endpoint Qualitative Mode of Action syntheses delivered by deadlines noted in SOW

6.2.3 Evaluation of Microarray Data: The Contractor shall prepare tables summarizing the available evidence using microarray data to investigate. The contractor shall evaluate the available studies using microarray data using the Systematic Omics Analysis Review (SOAR). The SOAR evaluation shall be used as guidance for determining if the data are appropriate for consideration in the assessment. At a minimum, these tables should include the relevant bibliographic information, description of study design/quality, SOAR scores, and dose-response information. These tables shall be updated as new data become available. The data used to create these evidence tables shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database. For considered microarray data, the Contractor shall perform pathway analyses and organize the available studies by potential modes of action.

Deliverables:
Summary tables of microarray studies
Pathway analysis for microarray data organized by modes of action

6.3 Endpoint – Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents related to endpoint considerations based upon reviewer comments. Reviewers

may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents/analyses related to endpoint considerations
Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)

Task 7: Efforts related to Risk Metric Considerations for Inorganic Arsenic

The objective of this task is to assist EPA in developing an IRIS toxicological review for inorganic arsenic. The toxicological review shall characterize risk metrics of inorganic arsenic exposure. Risk metrics are measures by which effects of inorganic arsenic exposure are quantified. Quantification of health effects in the IRIS toxicological review of inorganic arsenic will implement recommendations made by National Research Council in "Critical Aspects of EPA's IRIS Assessment of Inorganic Arsenic – Interim Report" with respect to. In addition, all applicable Agency guidance and formats should be used in preparing this draft toxicological review. When necessary, EPA will provide technical guidance to clarify specific requirements of the task.

Specific requirements of this task:

7.1 Risk Metric Dose-Response Analyses: The Contractor shall assist EPA in performing meta-analyses and dose-response analyses, in accordance with technical direction. The Contractor shall use materials developed by the EPA to perform requested dose-response analyses. The Contractor duties may include, but are not limited to, extracting data for dose-response analyses, performing dose-response analyses, and developing tables summarizing the results of dose-response analyses. The data used to perform dose-response analyses tables shall be organized and maintained on EPA's HERO database or within a database that is compatible with EPA's HERO database.

Deliverable:
Meta-analyses and dose-response analyses, as per technical direction

7.2 Risk Metric Response to Reviewer Comments: The Contractor shall assist EPA in preparing revised documents or analyses related to risk metric considerations based upon reviewer comments. Reviewers may include, but are not limited to, internal Agency reviewers, interagency reviewers, or public stakeholders. Revised versions of the documents may include "redline" revisions of documents related to stressor considerations and written responses to comments, as necessary.

Deliverables:
Revised documents/analyses related to risk metric considerations
Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	20 days after award
Task 3. Efforts related to Stressor Considerations for Inorganic Arsenic	
Task 3.1 – Stressor Considerations – Response to Reviewer Comments	
• Revised documents related to stressor considerations	2 weeks from receipt of reviewer comments
• Written responses to comment on documents related to stressor considerations (based upon technical direction)	2 weeks from receipt of reviewer comments
Task 4. Efforts related to Exposure Pathway Considerations for Inorganic Arsenic	
Task 4.1 - Exposure Pathway Model Considerations – Response to Reviewer Comments	
• Revised documents/models related to exposure pathway considerations	6 weeks from receipt of reviewer comments
• Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)	6 weeks from receipt of reviewer comments
Task 5. Efforts related to Receptor Considerations for Inorganic Arsenic	
Task 5.1 – Receptor Considerations - Sensitivity analysis	
• Sensitivity analyses describing the impact of receptor considerations on dose-response analyses	2 months from award of Work Assignment
Task 5.2 - Receptor Considerations – Response to Reviewer Comments	
• Revised documents/models related to exposure pathway considerations	4 weeks from receipt of reviewer comments
• Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)	4 weeks from receipt of reviewer comments
Task 6. Efforts related to Endpoint Considerations for Inorganic Arsenic	
Task 6.1 - Endpoint Synthesis Text	
Task 6.1.1 - Manage the drafting process	
• Endpoint synthesis section, including meta-analyses where possible	3 weeks from award of Work Assignment
Task 6.2 - Endpoint Qualitative Mode of Action Syntheses	

Task 6.2.1 - Endpoint Qualitative Mode of Action Syntheses Summary Tables	
• Summary tables on potential modes of action, including updates to incorporate new data	2 months from award of Work Assignment (updates as needed)
Task 6.2.2 - Endpoint Qualitative Mode of Action Synthesis	
• Endpoint Qualitative Mode of Action syntheses	6 weeks from award of Work Assignment
Task 6.2.3 - Evaluation of Microarray Data	
• Summary tables of microarray studies	1 months from award of Work Assignment
• Pathway analysis for microarray data organized by modes of action	1 month from award of Work Assignment
Task 6.3 - Endpoint Considerations – Response to Reviewer Comments	
• Revised documents/models related to endpoint considerations	5 weeks from receipt of reviewer comments
• Written responses to comment on documents related to endpoint considerations (based upon technical direction)	5 weeks from receipt of reviewer comments

Task 7. Efforts related to Risk Metric Considerations for Inorganic Arsenic	
Task 7.1 -Risk Metric Dose-Response Analyses	
• Meta-analyses and dose -response analyses, as per technical direction	2 months from award of Work Assignment
Task 7.2 – Risk Metric Considerations – Response to Reviewer Comments	
• Revised documents/models related to exposure pathway considerations	8 weeks from receipt of reviewer comments
• Written responses to comment on documents related to exposure pathway considerations (based upon technical direction)	8 weeks from receipt of reviewer comments

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Managers (WAMs):

Janice S. Lee, PhD
919-541-9458
Lee.JaniceS@epamail.epa.gov

Jeff Gift, PhD
919-541-4828
Gift.Jeff@epamail.epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;
VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;
INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?
RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;
UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.
CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.) Bibliographic identification of the study.

Study Identifiers:
Author(s):
Title:
Study Citation:
Storage location (e.g., library, facility archive, personal archive):

2.) Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)

3.) Summarize the study structure and methodology. What sampling techniques and statistical tests are used?

4.) Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.

5.) Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.

6.) Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:

Are research questions clearly stated; dependent and independent variables clearly defined?

Do the authors explain the type of data obtained from measures of the variables?

Are statistical methods adequately described; are they justified?

Is a source provided for the any statistical software used to analyze the data?

Is the purpose of the analysis clear?

Are any scoring systems described?

Are potential confounders adequately controlled for in the analysis?

Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?

Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-18

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Toxicological Review of Inorga
	Base Option Period Number 2	

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	Assessment Issues and Documents 1. Human Health As

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$995,395.00	8,730
Total:	$995,395.00	8,730

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 12/07/2015	$995,395.00	8,730
Cumulative Approved:	$995,395.00	8,730

Work Assignment Manager Name: Janice S. Lee (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-9458 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)		Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name William Yates (Signature) 2/09/2016 (Date)		Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-19

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Hexavalent Chromium
	Base Option Period Number 2	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: A. 1, B, D, E, G

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [ ] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 11/01/2013 To 10/31/2016 — Cost/Fee: — LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: — Cost/Fee: — LOE:

Cumulative Approved: — Cost/Fee: — LOE:

Work Assignment Manager Name: Catherine Gibbons (Signature) (Date)	Branch/Mail Code: Phone Number: 703-603-0704 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 703-347-8523 FAX Number: 703-347-8696
Other Agency Official Name: (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: Adam Meier (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2852 FAX Number: 513-487-2107

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
WA 2-19

TITLE: Preparation and Revision of the IRIS Draft Toxicological Review of Hexavalent Chromium (CAS No. 18540-29-9)

Specify Section & Paragraph SOW:

A. Assessment Issues and Documents
1. Human Health Assessment Documents
B. Risk Assessment Data Bases and Computer Tools exposure assessment
D. Analysis, Document and Issue Paper Preparation
E. Risk Assessment Support
G. Literature Search

PERIOD OF PERFORMANCE: *11/1/15 to 10/31/16*

I. PURPOSE

This work assignment is a continuation of work performed in the Option Period 1 under Work Assignment #0-19 and #1-19. The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD) related to the development of the Toxicological Review of Hexavalent Chromium. Specifically, support may include developing Sections 1 and 2 of a draft Toxicological Review on the potential health hazards of hexavalent chromium (by all routes of exposure) and the Integrated Risk Information System (IRIS) Summary for this chemical, providing support in addressing comments on the draft Toxicological Review following formal review steps, conducting literature updates relevant to this assessment, and performing technical edits. The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential health effects from hexavalent chromium by all exposure routes. This document shall include derivation of an oral reference dose (RfD), inhalation reference concentration (RfC), oral slope factor, and inhalation unit risk where scientifically feasible and provide justification for those instances where quantitative derivations are deemed infeasible or not necessary. This document shall also present information used to assign the cancer weight-of-evidence descriptor for hexavalent chromium. All applicable Agency guidance and formats should be used in the development of this draft document.

II. BACKGROUND

EPA's IRIS Program is an assessment program that evaluates qualitative and quantitative information on human health effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA provides science-based human health assessments to support the Agency's activities. The IRIS database contains hazard characterization and toxicity values for the first two steps of the risk assessment process—hazard identification and dose-response assessment. By combining IRIS toxicity values with information on chemical exposure, government and other entities can characterize health risks of chemicals.

EPA's process for developing IRIS assessments consists of: (1) draft development, which includes a public meeting focused on identifying the available scientific information; a comprehensive search of the scientific literature; release of preliminary materials (literature search and associated search strategies, evidence tables, and exposure-response figures); and a public meeting to discuss the early materials; (2) EPA-wide internal review; (3) science consultation on the draft assessment with other Federal agencies and the Executive Office of the President; (4) public review and comment, including a public meeting to discuss the draft assessment and draft peer review charge, and independent expert peer review; (5) revision of the assessment to address peer review and public

comments; (6) a second EPA-wide internal review and interagency discussion with other Federal agencies and the Executive Office of the President; and (7) posting of the final assessment to the IRIS website (www.epa.gov/iris/).

A Toxicological Review of Hexavalent Chromium, which assessed the health effects of both oral and inhalation exposures to hexavalent chromium, was posted to the IRIS database in 1998. A reassessment of hexavalent chromium was initiated in 2008 in light of new scientific information, with the oral assessment expedited due to EPA program office needs. This draft of the reassessment of the noncancer and cancer health effects associated with oral exposure to hexavalent chromium was produced on a separate track and was submitted for public comments and external peer review (see http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=221433). A draft of the Toxicological Review of Hexavalent Chromium by inhalation (and other non-oral) exposures was later initiated as a separate document from the draft Toxicological Review for oral exposures. However, it is now appropriate to combine and revise these documents into one draft Toxicological Review of Hexavalent Chromium by all routes of exposure. The existing draft assessments will be reorganized consistent with a modified Toxicological Review template that has been produced in response to comments provided by the National Academies of Science in their external expert review of the Toxicological Review of Formaldehyde. In addition, the Toxicological Review will be updated to included relevant literature identified in an updated comprehensive literature search of the health effects of hexavalent chromium by all exposures.

This PWS addresses the following steps of the IRIS process for assessment development: Development of the draft Toxicological Review (Step 1); Revision of the assessment in response to comments (Steps 2-6); and Preparation of an IRIS Summary (Step 5).

In developing the Toxicological Review and IRIS Summary, the Contractor shall follow applicable EPA guidance (see http://www.epa.gov/iris/backgrd.html).

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, statistics, and library science. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "*EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs* (QAPP)"; "*EPA Requirements for Quality Assurance Project Plans (QA/R-5)*"; "Appendix A. *Guidance on Quality Assurance Project Plans for Secondary Research Data*"; "*EPA 100/B-03/001: A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (2003)," and the addendum, "*Guidance for Evaluating and Documenting the Quality of Existing Scientific and Technical Information* (2012)."

The QAPP shall be submitted simultaneously with the Work Plan for approval.

Task 3: Update and Quality Assurance of Evidence Tables

The Contractor shall provide support to EPA in performing updates and quality assurance checks of tables that summarize organ-specific toxicity in human studies and animal bioassays (i.e., evidence tables) as well as tables presenting summaries of ADME (absorption, distribution, metabolism, and excretion) and genetic toxicity studies. Updates of evidence tables shall be performed to add new studies identified through literature search updates performed during development of the draft assessment or during review steps. Quality assurance checks shall include the following: comparison of table entries to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m^3), confirming effect levels, and inserting and verifying HERO links. For each health effect category, separate evidence tables will be developed (if data are available); only inhalation and oral routes of exposure will be considered. The quality assurance check should be performed by a scientist that was not involved in the initial development of the table being reviewed. These tables will be provided to the Contractor by the WAM.

Task 4: Technical Editing of the Draft Toxicological Review of Hexavalent Chromium and IRIS Summary

The Contractor shall conduct technical edits of the Toxicological Review prior to release for public comment/external peer review and prior to posting on the IRIS web site. The Contractor shall also conduct a technical edit of the IRIS Summary prior to posting.

Technical editing, which involves the reworking of written technical material for a specialized audience, may include: arranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc.; standardizing symbols; verifying and restyling reference citations where required; and cross-checking information in text, tables, and figures, as well as correcting errors in grammar, spelling, and punctuation. This work shall be performed according to EPA guidance related to the technical editing; the Handbook for Preparing NCEA Documents shall be used as a primary reference to resolve issues involving usage and style. All products will be formatted using current versions of IRIS Summary and Toxicological Review templates. The reference list shall be formatted according to the output in HERO (i.e., the HERO format supersedes the Handbook for Preparing EPA Documents). Technical editing includes:

a. Mechanical editing – Close reading of the manuscript to ensure correct grammar, spelling, syllabification, and punctuation; consistency of capitalization, spelling, and hyphenation; agreement of verbs and subjects; agreement of pronouns; correct use of adverbs and adjectives; beginning and ending quotation marks and parentheses; correct use of ellipsis; cross-checking contents with text to verify accuracy and consistency of headings, subheadings, and page numbers; and many other details of style.

b. Substantive editing – Involves any or all of the following: arranging or rearranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc; standardizing symbols; verifying and restyling reference citations; cross-checking information in the text to tables, figures, appendices, and references and correct apparent disagreements; correcting inconsistencies in format and style.

c. Checking references to ensure that all references cited in the text and only those references have been included in the reference section of the document and verifying accuracy, completeness, and adherence to established format. In the event that information is missing, consulting authors or procuring copies of cited material to complete reference.

d. HERO links – HERO links shall be added to any text in which links were not included.

The Contractor shall provide a final electronic mark-up (in 'Track Changes' format of Microsoft Word) of the draft Toxicological Review of Hexavalent Chromium and the IRIS Summary to the WAM no more than 20 days after receipt of the draft document from the WAM.

Task 5: Updates to Literature Search

The Contractor shall perform literature search updates during the review processes at regularly scheduled intervals during assessment development (i.e., through release for external peer review) and at least once after external peer review. The interval (i.e., number of months) between literature search updates shall be determined in consultation with the Contractor. The literature search strategy shall be consistent with the strategy for the initial hexavalent chromium literature search conducted by ICF and with the latest draft of the Handbook for IRIS Assessment Development. The Contractor shall add new references to HERO, tag references consistent with existing tags in HERO, and document the updated literature search strategy and findings.

If questions arise during the literature search and screening task (e.g., difficulties in narrowing down the number of "hits" from the search, questions about the relevance of certain types of papers or topics, retrieval of difficult to obtain documents or foreign language papers), the Contractor shall contact the WAM for further consultation.

Task 6: Maintenance of the HERO Database for Hexavalent Chromium Literature

The Contractor shall perform the following to ensure the HERO database is up to date with the most current Toxicological Review of Hexavalent Chromium:

- Ensure that all literature referenced in the IRIS document can be found in HERO
- Ensure that references listed in HERO for a "chromium" search but are not referenced in the IRIS document do not contain tags that suggest otherwise
- Ensure that references are appropriately tagged, both in their HERO listings and in the hyperlinks embedded in the document
- Ensure that retrieved pdfs of references in the IRIS document are uploaded to HERO

OPTIONAL TASKS

The following tasks are optional. If EPA determines the services under these tasks are required, the EPA WAM will initiate by issuing written technical direction. These optional tasks should be addressed in the technical proposal and included in the cost proposal of the work plan.

Optional Task 7: Synthesis of the Evidence for Selected Health Effects

Upon completion of Task 3, the Contractor shall develop a synthesis of the available evidence for selected health effect categories for which evidence tables have been generated, The Contractor shall refer to the latest draft of the Handbook for IRIS Assessment Development for guidance in developing this synthesis text (see section entitled "Evaluating the Overall Evidence of Each Effect"). Health effects information for effects with limited literature can be included in a section titled "Other Toxicological Effects." The text should reflect a synthesis of the overall findings for each health effect rather than a summary of individual studies.

The Contractor shall submit the draft syntheses to the WAM for review as they are completed. Based on comments from the WAM, the Contractor shall submit a final synthesis for each health effect section (except human inhalation exposure).

Optional Task 8: Support in Addressing Comments on the Toxicological Review following Various Review Steps

The Contractor shall provide support to the EPA in addressing comments received during various review steps, including Agency review, interagency review, external peer review, and public comment. EPA cannot anticipate the number or nature of comments that will be received at each review step or the specific type of Contractor support that will be required following any given review step. EPA estimates that support will consist of the following tasks: summarize comments by topic or issue, research special topics or issues that may be raised in comments, conduct additional BMD or other modeling/analysis as appropriate, revise the Toxicological Review in response to comments, and assist in developing written responses to comments. The Contractor may also be asked to populate Comment-Tracker, an Access database developed by EPA to manage comments (and responses) on the draft assessment. The Contractor may also be asked to attend the interagency review meeting (via teleconference) and take notes during that meeting for internal use. All of these tasks will require a quick turn-around time.

Optional Task 9: Preparation of IRIS Summary

Prior to final Agency review and interagency science discussion, the Contractor shall prepare the IRIS Summary. The IRIS Summary shall be developed using the latest IRIS Summary template (to be provided by the WAM) and instructions for IRIS Summary development in the SOPs. The IRIS Summary shall be generated by extracting appropriate text from the current draft Toxicological Review (i.e., the draft that reflects revisions in response to external peer review comments). Little new writing will be required. The WAM will provide the Contractor with the appropriate draft of the Toxicological Review to use in developing the IRIS Summary. The Contractor shall submit the draft IRIS Summary to the WAM for review.

The WAM will provide to the Contractor EPA's comments on the draft IRIS Summary. The Contractor shall revise the IRIS Summary based on EPA's comment and submit the revised final draft IRIS Summary to the WAM.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word. The literature search and electronic copies of the literature shall be provided via an Endnote database and uploaded to HERO.

V. DELIVERABLES AND SCHEDULE

Task	Deliverable Due Date
Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan and QAPP	20 days after award
Task 3: Update and Quality Assurance of Evidence Tables	No more than 20 days after discussion with WAM
Task 4: Technical Editing of the Draft Toxicological Review of Hexavalent Chromium and IRIS Summary	No more than 20 days after receipt of the draft Hexavalent Chromium Toxicological Review and no more than 10 days after receipt of the IRIS Summary from WAM
Task 5: Updates to Literature Search	For each update, no more than 30 days after initiation of literature search
Task 6: Maintenance of the HERO Database for Hexavalent Chromium Literature	To be performed concurrent with literature search updates
Optional Task 7: Synthesis of the Evidence for Selected Health Effects	45 days after discussion with the WAM. If synthesis sections are developed for multiple health effect categories, sections for individual health effects should be provided to the WAM as they are completed

Task	Deliverable Due Date
Optional Task 8: Support in Addressing Comments on the Toxicological Review following Various Review Steps	To be determined based on the nature of the Contractor support required
Optional Task 9: Preparation of IRIS Summary	7 days after final draft Toxicological Review is provided to the Contractor by EPA

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Catherine F. Gibbons, PhD
Telephone: 703-603-0704
Fax: 703-347-8689
e-mail: gibbons.catherine@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment (MC 8601P)
1200 Pennsylvania Ave. NW

Washington, DC 20460

Overnight Delivery location:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
Two Potomac Yard (N-7215)
2733 S. Crystal Drive
Arlington, VA 22202

Alternate WAM:

Susan Rieth
Telephone: 703-347-8582
Fax: 703-347-8689
e-mail: rieth.susan@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment (MC 8601P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Overnight Delivery location:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
Two Potomac Yard (N-7811)
2733 S. Crystal Drive
Arlington, VA 22202

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-19

☐ Other ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016	Hexavalent Chromium
	Base Option Period Number 3	

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: See Comments

Purpose:
- [X] Work Assignment
- [ ] Work Assignment Amendment
- [X] Work Plan Approval
- [ ] Work Assignment Close-Out
- [ ] Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:
A. Assessment Issues and Documents
1. Human Health Assessment Documents
B. Risk Assessment Data Bases and Computer Tools exposure assessment
D. Analysis, Document and Issue Paper Preparation

☐ Superfund — Accounting and Appropriations Data — [X] Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (Max 2): ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Contract Period	Cost/Fee	LOE
	11/01/2013 To 10/31/2016		
This Action:		$91,311.00	1,005
Total:		$91,311.00	1,005

Work Plan / Cost Estimate Approvals

		Cost/Fee	LOE
Contractor WP Dated:	11/20/2015	$91,311.00	1,005
Cumulative Approved:		$91,311.00	1,005

Work Assignment Manager Name: Catherine Gibbons (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	703-603-0704
	FAX Number:	
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	919-541-0207
	FAX Number:	
Other Agency Official Name (Signature) (Date)	Branch/Mail Code:	
	Phone Number:	
	FAX Number:	
Contracting Official Name William Yoder (Signature) Dec 24/15 (Date)	Branch/Mail Code:	
	Phone Number:	513-487-2852
	FAX Number:	513-487-2107

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-19

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base X Option Period Number	IRIS Cr(VI) Draft Development

Contractor	Specify Section and paragraph of Contract SOW
ICF INCORPORATED, L.L.C.	A1, B, D, E, G

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☐ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:
The purpose of this amendment is to change "Optional Task 7" to "Task 7" and extend it to the recruitment of external subject-matter expert scientists to complete the task. Optional Task 9 was also removed.

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

SFO (*Max 2*) ☐

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee:	LOE:
11/01/2013 To 10/31/2016		
This Action:		
Total:		

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee	LOE:
Cumulative Approved:	Cost/Fee	LOE:

Work Assignment Manager Name: Catherine Gibbons (Signature) (Date)		Branch/Mail Code: Phone Number: 703-603-0704 FAX Number:
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Other Agency Official Name (Signature) (Date)		Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates William Yates (Signature)	6-9-2016 (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number:

PERFORMANCE WORK STATEMENT
CONTRACT NO. EP-C-14-001
Amendment 1 to WA 2-19

TITLE: Preparation and Revision of the IRIS Draft Toxicological Review of Hexavalent Chromium (CAS No. 18540-29-9)

Specify Section & Paragraph SOW:

A. Assessment Issues and Documents
1. Human Health Assessment Documents
B. Risk Assessment Data Bases and Computer Tools exposure assessment
D. Analysis, Document and Issue Paper Preparation
E. Risk Assessment Support
G. Literature Search

PERIOD OF PERFORMANCE: *11/1/15 to 10/31/16*

I. PURPOSE

This work assignment is a continuation of work performed in the Option Period 1 under Work Assignment #0-19 and #1-19. The purpose of this Work Assignment is to provide continued services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD) related to the development of the Toxicological Review of Hexavalent Chromium. Specifically, support may include developing Sections 1 and 2 of a draft Toxicological Review on the potential health hazards of hexavalent chromium (by all routes of exposure) and the Integrated Risk Information System (IRIS) Summary for this chemical, providing support in addressing comments on the draft Toxicological Review following formal review steps, conducting literature updates relevant to this assessment, and performing technical edits. The draft Toxicological Review shall provide a summary of the state-of-the-science pertaining to potential health effects from hexavalent chromium by all exposure routes. This document shall include derivation of an oral reference dose (RfD), inhalation reference concentration (RfC), oral slope factor, and inhalation unit risk where scientifically feasible and provide justification for those instances where quantitative derivations are deemed infeasible or not necessary. This document shall also present information used to assign the cancer weight-of-evidence descriptor for hexavalent chromium. All applicable Agency guidance and formats should be used in the development of this draft document. ***This amendment provides for continuation and extension of work initiated under Contract EP-C-14-001 WA 2-19.***

II. BACKGROUND

EPA's IRIS Program is an assessment program that evaluates qualitative and quantitative information on human health effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA provides science-based human health assessments to support the Agency's activities. The IRIS database contains hazard characterization and toxicity values for the first two steps of the risk assessment process—hazard identification and dose-response assessment. By combining IRIS toxicity values with information on chemical exposure, government and other entities can characterize health risks of chemicals.

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This PWS addresses the following steps of the IRIS process for assessment development: Development of the draft Toxicological Review (Step 1); Revision of the assessment in response to comments (Steps 2-6); and Preparation of an IRIS Summary (Step 5).

In developing the Toxicological Review and IRIS Summary, the Contractor shall follow applicable EPA guidance (see http://www.epa.gov/iris/backgrd.html).

III. STATEMENT OF WORK

The work plans for Tasks 1-6 and Optional Task 8 have not changed substantively. The Contractor is not required to submit a new work plan for these unaltered tasks.

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

This task was completed under WA 2-19. No further work is expected under this task.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, statistics, and library science. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

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a. Mechanical editing – Close reading of the manuscript to ensure correct grammar, spelling, syllabification, and punctuation; consistency of capitalization, spelling, and hyphenation; agreement of verbs and subjects; agreement of pronouns; correct use of adverbs and adjectives; beginning and ending quotation marks and parentheses; correct use of ellipsis; cross-checking contents with text to verify accuracy and consistency of headings, subheadings, and page numbers; and many other details of style.

b. Substantive editing – Involves any or all of the following: arranging or rearranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc; standardizing symbols; verifying and restyling reference citations; cross-checking information in the text to tables, figures, appendices, and references and correct apparent disagreements; correcting inconsistencies in format and style.

c. Checking references to ensure that all references cited in the text and only those references have been included in the reference section of the document and verifying accuracy, completeness, and adherence to established format. In the event that information is missing, consulting authors or procuring copies of cited material to complete reference.

d. HERO links – HERO links shall be added to any text in which links were not included.

The Contractor shall provide a final electronic mark-up (in 'Track Changes' format of Microsoft Word) of the draft Toxicological Review of Hexavalent Chromium and the IRIS Summary to the WAM no more than 20 days after receipt of the draft document from the WAM.

Task 5: Updates to Literature Search

The Contractor shall perform literature search updates during the review processes at regularly scheduled intervals during assessment development (i.e., through release for external peer review) and at least once after external peer review. The interval (i.e., number of months) between literature search updates shall be determined in consultation with the Contractor. The literature search strategy shall be consistent with the strategy for the initial hexavalent chromium literature search conducted by ICF and with the latest draft of the Handbook for IRIS Assessment Development. The Contractor shall add new references to HERO, tag references consistent with existing tags in HERO, and document the updated literature search strategy and findings.

If questions arise during the literature search and screening task (e.g., difficulties in narrowing down the number of "hits" from the search, questions about the relevance of certain types of papers or topics, retrieval of difficult to obtain documents or foreign language papers), the Contractor shall contact the WAM for further consultation.

Task 6: Maintenance of the HERO Database for Hexavalent Chromium Literature

The Contractor shall perform the following to ensure the HERO database is up to date with the most current Toxicological Review of Hexavalent Chromium:

- Ensure that all literature referenced in the IRIS document can be found in HERO
- Ensure that references listed in HERO for a "chromium" search but are not referenced in the IRIS document do not contain tags that suggest otherwise
- Ensure that references are appropriately tagged, both in their HERO listings and in the hyperlinks embedded in the document
- Ensure that retrieved pdfs of references in the IRIS document are uploaded to HERO

~~**Optional**~~ **Task 7: Synthesis of the Evidence for Selected Health Effects**

Task 7 is no longer considered optional under this amendment. Prior to beginning work on Task 7, the Contractor shall hold a task initiation meeting with the EPA WAM to discuss the approach, products, and expectations.

The Contractor shall identify, recruit, and manage expert scientists to author health effect category synthesis sections, or to co-author and revise sections for which drafts have already been generated. The Contractor shall be responsible for ensuring timely communication is passed between the EPA WAM and the experts so that technical clarification can be offered and interaction between EPA and the experts can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

The synthesis sections shall evaluate (1) the relationship between hexavalent chromium exposure and lung cancer mortality in cohorts exposed occupationally via inhalation at chromate production plants, and (2) chemical carcinogenesis, and in particular modes of action for cancer following oral exposures to hexavalent

chromium, in the gastrointestinal (GI) tract of animals and humans. The authors of each section shall have a Ph.D., M.D., or equivalent in a relevant field and ideally some prior experience in evaluating the effects of hexavalent chromium exposures. Potential authors shall be asked to submit a biosketch for assessing their qualifications. EPA approval of the authors suggested by the Contractor will be required to ensure that they possess the desired/minimum qualifications.

Because it is important that each health effect category synthesis section conforms to guidelines set by the IRIS program and that there is consistency in the approaches used across all of the health effect category synthesis sections included in the draft Toxicological Review, it is expected that section authors will communicate regularly with the EPA WAM through weekly teleconferences and additional email and telephone correspondence as necessary. Section authors will also participate (by teleconference) in weekly meetings of the hexavalent chromium assessment team and in biweekly meetings of the hazard-relevant IRIS disciplinary workgroup. The Contractor shall manage the section authors and ensure that necessary communications occur and that deliverables are provided to the EPA WAM in a timely manner, according to the schedule set at the task initiation meeting.

The EPA assumes primary authorship in the writing process, and contributing authors are listed in the final document as appropriate. EPA will approve (or disapprove) each of the expert authors performing this work within two days of notification of a potential candidate.

~~Upon completion of Task 3, the Contractor shall develop a synthesis of the available evidence for selected health effect categories for which evidence tables have been generated. The Contractor shall refer to the latest draft of the Handbook for IRIS Assessment Development for guidance in developing this synthesis text (see section entitled "Evaluating the Overall Evidence of Each Effect"). Health effects information for effects with limited literature can be included in a section titled "Other Toxicological Effects." The text should reflect a synthesis of the overall findings for each health effect rather than a summary of individual studies.~~

~~The Contractor shall submit the draft syntheses to the WAM for review as they are completed. Based on comments from the WAM, the Contractor shall submit a final synthesis for each health effect section (except human inhalation exposure).~~

OPTIONAL TASK

The following task is optional. If EPA determines the services under this tasks is required, the EPA WAM will initiate by issuing written technical direction. This optional task should be addressed in the technical proposal and included in the cost proposal of the work plan.

Optional Task 8: Support in Addressing Comments on the Toxicological Review following Various Review Steps

The Contractor shall provide support to the EPA in addressing comments received during various review steps, including Agency review, interagency review, external peer review, and public comment. EPA cannot anticipate the number or nature of comments that will be received at each review step or the specific type of Contractor support that will be required following any given review step. EPA estimates that support will consist of the following tasks: summarize comments by topic or issue, research special topics or issues that may be raised in comments, conduct additional BMD or other modeling/analysis as appropriate, revise the Toxicological Review in response to comments, and assist in developing written responses to comments. The Contractor may also be asked to populate Comment-Tracker, an Access database developed by EPA to manage comments (and responses) on the draft assessment. The Contractor may also be asked to attend the interagency review meeting (via teleconference) and take notes during that meeting for internal use. All of these tasks will require a quick turn-around time.

[Optional Task 9: Preparation of IRIS Summary has been deleted from the PWS]

~~Prior to final Agency review and interagency science discussion, the Contractor shall prepare the IRIS Summary. The IRIS Summary shall be developed using the latest IRIS Summary template (to be provided by the WAM) and instructions for IRIS Summary development in the SOPs. The IRIS Summary shall be generated by extracting appropriate text from the current draft Toxicological Review (i.e., the draft that reflects revisions in response to external peer review comments). Little new writing will be required. The WAM will provide the Contractor with the appropriate draft of the Toxicological Review to use in developing the IRIS Summary. The Contractor shall submit the draft IRIS Summary to the WAM for review.~~

~~The WAM will provide to the Contractor EPA's comments on the draft IRIS Summary. The Contractor shall revise the IRIS Summary based on EPA's comment and submit the revised final draft IRIS Summary to the WAM.~~

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word. The literature search and electronic copies of the literature shall be provided via an Endnote database and uploaded to HERO.

V. DELIVERABLES AND SCHEDULE

Task	Deliverable Due Date
Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan and QAPP	20 days after award
Task 3: Update and Quality Assurance of Evidence Tables	No more than 20 days after discussion with WAM
Task 4: Technical Editing of the Draft Toxicological Review of Hexavalent Chromium and IRIS Summary	No more than 20 days after receipt of the draft Hexavalent Chromium Toxicological Review and no more than 10 days after receipt of the IRIS Summary from WAM
Task 5: Updates to Literature Search	For each update, no more than 30 days after initiation of literature search
Task 6: Maintenance of the HERO Database for Hexavalent Chromium Literature	To be performed concurrent with literature search updates
~~Optional~~ Task 7: Synthesis of the Evidence for Selected Health Effects	45 days after discussion with the WAM. If synthesis sections are developed for multiple health effect categories, sections for individual health effects should be provided to the WAM as they are completed
Optional Task 8: Support in Addressing Comments on the Toxicological Review following Various Review Steps	To be determined based on the nature of the Contractor support required
~~Optional Task 9: Preparation of IRIS Summary~~	~~7 days after final draft Toxicological Review is provided to the Contractor by EPA~~

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy
(2) Selection of Agency priorities
(3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Catherine F. Gibbons, PhD
Telephone: 703-603-0704
Fax: 703-347-8689
e-mail: gibbons.catherine@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment (MC 8601P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Overnight Delivery location:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
Two Potomac Yard (N-7215)
2733 S. Crystal Drive
Arlington, VA 22202

Alternate WAM:

Susan Rieth
Telephone: 703-347-8582

Fax: 703-347-8689
e-mail: rieth.susan@epa.gov

Mailing Address:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment (MC 8601P)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Overnight Delivery location:
U.S. Environmental Protection Agency
Office of Research and Development
National Center for Environmental Assessment
Two Potomac Yard (N-7811)
2733 S. Crystal Drive
Arlington, VA 22202

EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 2-19

☐ Other ☒ Amendment Number: 000001

Contract Number	Contract Period	Title of Work Assignment/SF Site Name
EP-C-14-001	11/01/2013 To 10/31/2016 Base Option Period Number 2	Cr6 draft dev. Amendment 1

Contractor: ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW: Section A, Subsection 1

Purpose:
- ☐ Work Assignment
- ☒ Work Assignment Amendment
- ☒ Work Plan Approval
- ☐ Work Assignment Close-Out
- ☐ Incremental Funding

Period of Performance: From 11/01/2015 To 10/31/2016

Comments:
Amendment to original PWS (adds task 7 and removes an optional task)

☐ Superfund — Accounting and Appropriations Data — ☒ Non-Superfund

SFO (*Max 2*): ☐

Note: To report additional accounting and appropriations date use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 11/01/2013 To 10/31/2016	$0.00	0
This Action:	$44,030.00	346
Total:	$44,030.00	346

Work Plan / Cost Estimate Approvals

	Cost/Fee	LOE
Contractor WP Dated: 06/30/2016	$44,030.00	346
Cumulative Approved:	$44,030.00	346

Work Assignment Manager Name: Catherine Gibbons (Signature) (Date)	Branch/Mail Code: Phone Number: 703-603-0704 FAX Number:
Project Officer Name: Melissa Revely-Wilson (Signature) (Date)	Branch/Mail Code: Phone Number: 919-541-0207 FAX Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: FAX Number:
Contracting Official Name: William Yates (Signature) (Date)	Branch/Mail Code: Phone Number: 513-487-2055 FAX Number: